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Development and validation of a new questionnaire for the assessment of patients with diabetic foot disease: The Diabetic Foot Questionnaire (DiaFootQ)

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ABSTRACT

Background: The epidemiology data and global burden of diabetic foot disease underscores the need for effective prevention strategies, which requires an early diagnosis. Patient-reported outcome measures are instruments based on a simple format, which favours their application. Currently, there is an absence of instruments with a broad enough scope to capture the diverse aspects involved in diabetic foot disease.
Objectives: To develop a questionnaire for the assessment of patients with diabetic foot disease and carry out an analysis of its validity and reliability.
Methods: The study was developed in two stages. Stage 1: the Delphi Panel was composed of 22 experts. The questionnaire is made up of 25 questions selected, after three rounds, from an initial sample of 68 questions. Stage 2: A validation study was performed. With a sample of 273 subjects, an exploratory factor analysis and an analysis of internal consistency, items response, and validity were carried out using the Diabetes Quality of Life, SF-12v2, Foot Function Index and EuroQol EQ5D questionnaires. Measurements of error and sensitivity to change were also analyzed.
Results: A 25-item questionnaire (DiaFootQ) was developed. It comprised two dimensions: 1) lifestyle and function; and 2) footwear and foot self-care. Sample (n=273) mean age was 69.77 years (±11.08). The internal consistency of DiafootQ was α=0.916, and item response values were ICC=0.862–0.998. External validity correlation levels ranged from r=0.386 to r=0.888.
Conclusion: DiaFootQ was developed. Integrating the main aspects involved in diabetic foot disease could help to detect more accurately the risk or severity of these patients. DiaFootQ is a well-structured, valid, and reliable tool whose use should be promoted in clinical and research settings.

What is the contribution of this paper?

This study introduces a novel questionnaire for assessing diabetic foot disease patients, developed through the Delphi method. Rigorous validation, adhering to COSMIN recommendations, demonstrated excellent psychometric properties, filling a gap in comprehensive outcome measures for this condition. Existing patient-reported measures mostly focus on specific variables, overlooking complete evaluation; this tool offers insights into foot health awareness, lifestyle habits, footwear, and disability outcomes within a single questionnaire. The fact that it was developed in English and validated in a primary health center with diabetic foot patients enhances its widespread applicability. This work presents a significant contribution to understanding diabetic foot disease and offers a valuable tool for clinicians and researchers alike, with implications for improving patient care and outcomes research on a global scale.

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1. Introduction

Diabetes mellitus (DM) is a chronic metabolic disease with a global incidence of 451 million people registered in 2018 [1] and an increasing prevalence trend, with a recent study indicating that it has increased significantly since 1990 in the 27 EU countries and the UK [2].

Diabetic foot disease (DFD) is a chronic complication of DM that presents with infection, ulceration or tissue destruction of the foot, as a result of diabetic neuropathy and peripheral arterial disease [3]. In 2016, over 131 million people (1.7 % of the global population) had diabetes related to lower extremity complications, and, as an example of its economic impact, in the UK, 1£ out of every 140£ spent in the National Health Service was spent in diabetic foot problems (mostly foot ulcers) [4]. One third of the whole diabetic population will develop a diabetic foot ulcer at least once in their lifetime; more than 50 % of these patients will develop an infection, which increases the likelihood of amputation [5]. Less than 50 % of amputees survive within 5 years, exceeding the mortality rate of most cancers [6].

Early diagnosis plays a key role in DFD patients, as it helps in the selection and implementation of adequate prevention and treatment strategies. This requires instruments that can measure variables of high value related to the patient's health status. These instruments can be divided into two groups: 1) those that provide objective information without the influence of external judgement, and 2) those that are based on data provided by the patients themselves: patient reported outcome measures (PROMs) [7].

PROMs are essentially questionnaires which report variables such as health status, quality of life, symptoms, or satisfaction with treatment [8]. Due to their low cost and feasible acquisition and distribution, PROMs allow screening a larger and more heterogeneous sample with lower time consumption [9]. Two recent systematic reviews [10,11] highlighted the need to develop specific questionnaires for the assessment of DFD, as none of the existing questionnaires address all the biopsychosocial and pathological factors that influence DFD. Aspects such as lifestyle or footwear habits are not included in any PROM designed for DFD patients, which seems essential due to the benefits of physical activity, diet and footwear interventions in the improvement of diabetes complications [12,13].

The existence of a valid and reliable questionnaire specifically designed for DFD patients is necessary for their assessment, since the degree or the severity of this complication could be more accurately measured. An instrument that allows evaluating the level of affectation that the patient perceives as a consequence of their pathology would allow different health professionals (such as podiatrists, nurses or doctors, among others) to assess the personal impact perceived by the patient and evaluate any potential changes that result from their clinical intervention.

The main objective of this study was to develop a specific questionnaire to assess the level of impairment perceived by patients with diabetic foot as a consequence of their pathology. Another objective pursued by this study was to analyze the structural and psychometric characteristics (reliability [internal validity, item response], validity, error measures, factor analysis, construct validity) of the developed questionnaire.

2. Material and methods

2.1. Phase I: elaboration of the questionnaire according to the Delphi methodology

This study presents a descriptive, cross-sectional and observational design divided into two phases. The first part was the construction of a questionnaire for the assessment and follow-up of patients with diabetic foot using the Delphi methodology [14], based on the Guidance on Conducting and Reporting Delphi Studies (CREDES) [15]. The panel was not conducted face-to-face, guaranteeing the anonymity of all participants and the free expression of the participants, and minimizing the influence of participants who could be considered opinion leaders [16–18]. The Ethics Committee of the University of Malta approved this study, which was conducted following the recommendations of the Declaration of Helsinki under the ethical principles for research on human subjects. All participants signed an informed consent before participating in the study, and the data were used under Organic Law 3/2018 on Data Protection, which is applicable in Spain, where the documentation is guarded.

2.1.1. Selection of panel members

For the selection of the panel members, specialists with more than ten years of experience in the assessment and treatment of DFD were involved, including clinicians with different profiles (endocrinologists, primary care physicians, vascular surgeons, podiatrists, nurses and physiotherapists). The Delphi methodology recommends a number of experts between 10 and 100. A total of 79 experts were initially contacted. Based on the availability of the experts and the compliance with the established deadlines, this study had the final participation of 22 experts. The inclusion criteria were: 1) experience in the treatment and assessment of patients with DFD in the last 10 years, and 2) being a native English speaker (or with an equivalent level of certification).

2.1.2. Elaboration of the questionnaire

An analysis of the main variables included in the literature in the last 15 years related to DFD was carried out to develop the questionnaire. The initial version of the questionnaire consisted of 68 questions with a 5-point Likert scale ranging from 0 to 4 (0=total disagreement, 2=neither agreement nor disagreement, 4=total agreement). Before sending it to the group of experts, it was sent to two experts in clinical language (anonymous and not related to the experts of the Delphi panel), in order to identify whether the questions presented any limitation or problem in comprehension. Following the experts' recommendations, slight modifications were made to some of the questions, and the questionnaire was generated with 68 questions in Google Forms. It was sent to all pre-selected experts, and they were given two months to respond to the questionnaire. In this first round, they were asked to analyze the level of relevance of each question for the assessment and follow-up of diabetic foot patients on a scale of 0–5. A section was provided to allow the experts to make comments [14–16].

In the first round, questions with a consensus to be included by at least 80 % were kept in the questionnaire, whereas questions that did not reach a consensus greater than 20 % were excluded. In the next round, the experts were asked to rank the questions in order of relevance to the assessment and follow-up of a patient with DFD. In addition, they were asked whether they missed any essential questions from the previous round. The response time for this second round was four weeks. With the answers obtained, the scores were summed according to the position of the question in each expert's list. A total of 70 % of the questions with the highest scores were selected. In the last round, the experts were again asked to rank the questions from highest to lowest according to the level of relevance for the assessment and follow-up of a patient with DFD. The response time was four weeks. The 25 questions with the highest scores were selected. After selecting the 25 questions that would make up the final questionnaire, a pilot study was conducted with 25 participants to evaluate and optimize the understanding of the final version of the questionnaire [17,18].

2.2. Phase II: Diabetic Foot Questionnaire (DiaFootQ) validation study

2.2.1. Participants

All patients included were adults (>18 years) attending the Diabetic Foot Unit of the Birkirkara Health Centre (Birkirkara, Malta) with type 2 DM, diagnosed with DFD under informed consent. Pregnant women and patients with cognitive impairment, dementia or visual impairment, which would prevent them from replying, were excluded.

2.2.2. External validity

To analyze the criteria validity of the DiaFootQ questionnaire, the following questionnaires were included, all with adequate psychometric properties:

- The Diabetes Quality of Life (DQoL) [19,20]: The brief DQoL serves as a tool for quickly screening patients for specific treatment-related problems and predicting self-reported diabetes care behaviours and satisfaction with diabetes control as effectively as the full version.
- Foot Function Index (FFI) [21]: This questionnaire consists of 23 self-reported items divided into three subcategories based on patient values for: pain, disability, and activity limitation.
- SF-12v2 [22–24]: The SF-12 v2 questionnaire comprises 12 items that cover 8 domains, and 2 summary measures can be derived: the Physical Component Summary score (PCS-12) and the Mental Component Summary score (MCS-12).
- EuroQoL [25–27]: The EuroQoL is a standardized instrument that measures health outcomes and includes five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.

2.3. Data collection

All participants completed the DiaFootQ, DQoL, FFI, SF-12v2 and EuroQoL questionnaires. In addition, in order to calculate the reliability of the questionnaire, following the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN) [28], the DiaFootQ questionnaire was administered again with a difference of 5 days between the first and the second measurement. Data were collected between October 2022 and January 2023. Two blinded investigators external to the study performed the data collection.

2.4. Data analysis

A frequency analysis of some of the descriptive characteristics of the sample, such as sex, education level or use of pharmacological treatment, was performed. Mean and standard deviation were calculated for the age of participants, duration of diabetes diagnosis, and the assessment instruments used in this study: DiaFootQ, DQoL, FFI, SF-12 and EuroQoL. The Kolmogorov-Smirnov test was used to calculate the sample distribution. The significance level was set at $p \leq 0.05$.

To analyze the factor structure and construct validity, the principal component extraction method was used. The following criteria were used to extract the different factors of the questionnaire: eigenvalue >1.0, accounting for >10 % of variance and a screen plot inflexion point.

The internal consistency of the DiaFootQ and its factors was analyzed using Cronbach's α. The Intraclass Correlation Index (ICC) was used to calculate the item response for each component of the DiaFootQ. The following scale was used to classify the different reliability values of the DiaFootQ: excellent: ≥0.80; good: 0.60–0.80; moderate: 0.40–0.60; poor: ≤0.40. The measure of error calculated was the standard error of measurement (SEM) using the following formula: $SEM = s\sqrt{1 - r}$, where the score's standard deviation was "s", and "r" was Pearson's correlation coefficient. The Minimal detectable change 90 (MDC90) was used to calculate the tool's sensitivity using the formula: $MDC90 = SEM \times \sqrt{2} \times 1.65$. The ceiling or floor effect was considered when at least 15 % of the participants reached the maximum or minimum DiaFootQ value, respectively.

The criterion validity of DiaFootQ was analyzed using the questionnaires: Diabetes Quality of Life (DQoL), Foot Function Index (FFI), SF-12 v2 and EQ-5D. Pearson's correlation coefficient was calculated. Correlation indexes were classified according to the following scale [29]: $r \geq 0.75$ (strong); $0.50 \leq r \leq 0.74$ (moderate); $r \leq 0.49$ (poor).

Recommendations from the literature suggest that the validation study should be conducted with at least ten subjects for each questionnaire item [30]. Considering that the DiaFootQ has 25 items, the minimum number needed was 250 participants. This study was conducted with 273 participants. The statistical data processing software SPSS (V.23.0) was used to perform the statistical analyses.

3. Results

3.1. Elaboration of the questionnaire

After the first round, the questionnaire with 68 questions was sent to a total of 79 experts. The number of experts who sent their responses in time was 53 (67.08 %). The number of questions included was 56. These were sent to the experts who responded to the previous round, and 31 responses were received (58.49 %). The number of questions included in the last round was 40, and the number of responses received was 22 (70.96 %), which were used to compose the final version of the DiaFootQ questionnaire. Therefore, a final group of 22 experts constituted the Delphi panel; the disciplines they belonged to and the percentage of experts representing each of them were: podiatrists (27 %), family doctors (23 %), endocrines (18 %), nurses (18 %), physiotherapists (9 %) and vascular surgeons (5 %). The flowchart of the elaboration and selection of the questions to compose the final questionnaire is presented in Fig. 1.

Supplementary Material 1 presents the 68 questions that were initially part of the development of the questionnaire and the process of elimination and selection. The final version of the DiaFootQ questionnaire includes 25 questions with a 5-point Likert scale ranging from 0 to 4 to evaluate each question, with 0 being the minimum DiaFootQ score, while the maximum score is 100, where the highest score implies a better state of health and function of the feet, higher quality of life and better self-care, as perceived by the DFD patient. Question 24 is scored in reverse. The final version of the DiaFootQ questionnaire is presented in Appendix A.

3.2. Validation of the questionnaire

Table 1 shows the description of the sample in terms of descriptive characteristics identified by frequency of occurrence, such as the sex distribution of the participants (only two categories were present), education level and type of pharmacological treatment. A total of n=273 people participated in this study.

Table 2 shows the descriptive characteristics of the sample. The number of respondents with the minimum DiaFootQ score was 6, while 11 participants reached the maximum score. This represents 2.19 % and 4.03 %, respectively, thus it can be stated that the floor-ceiling effect of the DiaFootQ was not relevant. The average time to complete the questionnaire was 4.26 (±0.871) minutes.

To analyze factor structure and construct validity, the principal components method was used, obtaining a Kaiser-Meyer-Olkin test value of 0.718 and a Chi-square value of 1595.118 in Bartlett's test of sphericity, with 300 degrees of freedom. All calculations showed a significance value of $p < 0.001$.

In the structural analysis, 2 factors were observed, which fulfilled the criteria for extraction. Table 3 shows that the variance explained between the two factors was 26.124 % (14.070 % and 12.054 %, respectively), as well as the loadings of each item for each factor identified in the DiaFootQ model. This result led to the development of the two dimensions conforming the questionnaire: the first dimension, named 'Lifestyle and Function', was composed of Items 5, 9–21 and 25; the second dimension, named 'Footwear and Foot Self-care', was composed of Items 1–4, 6–8, and 22–24. Fig. 2 presents the sedimentation plot of all items that comprised the DiaFootQ questionnaire.

Regarding the reliability values of the DiaFootQ, the internal consistency value of the questionnaire was 0.916, while the ICC values of item response ranged from 0.862 (Item 9) to 0.998 (Item 25). When analyzing the error measures and sensitivity, values of SEM = 1.271 and MDC90 = 2.964 were observed.

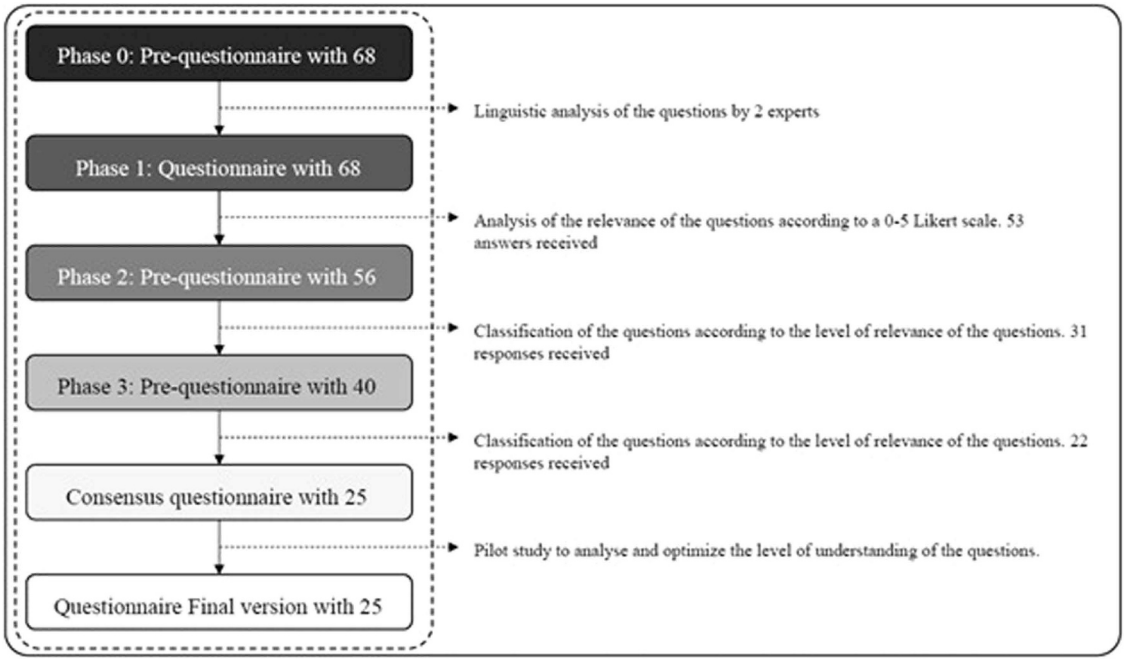

Fig. 1. Flowchart of the process of elaboration, filtering and selection of the questions of the questionnaire according to the Delphi methodology.

Table 1
Descriptive characteristics of the sample according to their frequency of use.

		Frequency	Percentage	Cumulative percentage
Sex	Male	152	55.7	55.7
	Female	121	44.3	100.0
Education level	Primary education	155	56.8	56.8
	Secondary education	98	35.9	92.7
	Higher education	12	4.4	97.1
	Other	2	.7	97.8
	None	6	2.2	100.0
Pharmacological treatment	Less than 3 months	6	2.2	72.9
	3–6 months	33	12.1	85.0
	6–12 months	35	12.8	97.8
	More than 1 year	199	72.9	100.0
N	273			

Table 2
Descriptive characteristics of the sample (mean, standard deviation and confidence intervals).

		Min	Max	Mean	SD
Age (years)		37	94	69.77	11.08
Duration of diabetes mellitus (years)		0	50	15.00	10.34
DiaFootQ		0	100	65.99	12.70
DQoL		4	160	94.51	29.263
FFI	Index	3	65	33.49	18,533
	Pain	0	41	14.63	11,614
	Disability	0	47	16.01	12,263
	Limit Activity	0	17	5.47	4030
SF−12	Physical Function	16.68	63.90	32.46	14,83
	Physical Role	18.87	64.61	42.23	12,91
	Bodily Pain	27.62	67.88	48.76	12,53
	General Health	16.18	65.70	40.95	18,81
	Vitality	11.35	68.81	34.47	17,37
	Social Functioning	21.87	65.73	42.42	12,99
	Emotional Role	17.43	64.84	39.32	17,03
	Mental Health	29.21	75.48	51.05	12,18
	Physical Component State	22.11	67.16	47.07	14,11
	Mental Component state	20.32	62.91	34.32	12,23
EuroQol VAS		0.280	1.000	0.76	0.175
EuroQol 5D		28.00	97.00	75.82	17.487
N		273			

The Diabetes Quality of Life (DQoL), Foot Function Index (FFI), SF-12v2 and EuroQol-5D questionnaires were used to calculate external validity. Table 4 shows the correlation levels between the DiaFootQ and the other instruments used. Correlation levels with the SF-12v2 were r=0.386–0.729, EuroQoL r=0.878–0.888, DQoL r=0.792 and FFI r=0.775–0.847. For further details, see Table 4.

4. Discussion

The main objective of the present study was to develop and validate a new tool for assessing and following up patients with DFD. The DiaFootQ questionnaire is the final result of a process that began with a review of the main variables for assessing and following up patients with DFD, which has been used in the scientific literature and clinical practice since the last 15 years.

After developing a preliminary questionnaire of 68 questions, and with the participation of 22 experts in the treatment, assessment and follow-up of patients with DFD, the 25 final questions that make up the DiaFootQ were identified. The psychometric characteristics observed in the DiaFootQ questionnaire define it as a tool with two factors: acceptable goodness of fit, accuracy in measuring identifiable changes in patients with DFD and good reliability levels (internal validity and item response).

Table 3
Self-value and variance explained by each of the items of the DiaFootQ questionnaire.

Component	Initial self-values			Extraction sums of squared loads		
	Total	% of variance	% cumulative	Total	% of variance	% cumulative
1	3.518	14.070	14.070	3.518	14.070	14.070
2	3.014	12.054	26.124	3.014	12.054	26.124
3	2.057	8.227	34.352			
4	1.889	7.557	41.908			
5	1.569	6.275	48.183			
6	1.283	5.134	53.317			
7	1.198	4.793	58.111			
8	0.994	3.976	62.087			
9	0.871	3.484	65.571			
10	0.795	3.181	68.752			
11	0.781	3.125	71.877			
12	0.743	2.972	74.848			
13	0.674	2.696	77.544			
14	0.628	2.511	80.055			
15	0.569	2.277	82.333			
16	0.554	2.218	84.550			
17	0.539	2.155	86.706			
18	0.502	2.009	88.715			
19	0.492	1.969	90.684			
20	0.439	1.758	92.442			
21	0.430	1.719	94.161			
22	0.406	1.622	95.783			
23	0.384	1.534	97.317			
24	0.367	1.468	98.786			
25	0.304	1.214	100.000			

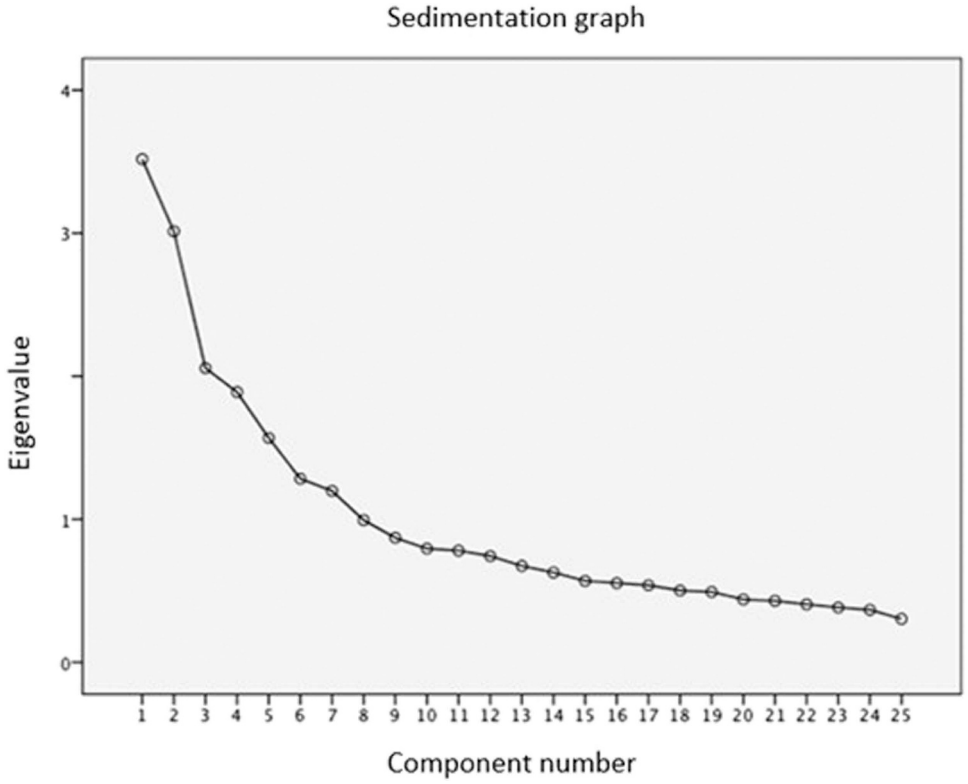

Fig. 2. Sedimentation graph for each of the items included in the DiaFootQ final version.

The external validity shows that the correlation levels range from poor to moderate. The DiaFootQ questionnaire fits perfectly into a protocol for assessing patients with DFD. However, it would not be necessary to include the EuroQoL tool, or any other tool that assesses the quality of life in such a protocol, since the correlation levels with this tool were excellent.

Two dimensions were extracted from the structural analysis: 'Lifestyle and function' and 'Footwear and foot self-care'. The former focuses on variables related to disability, socioeconomic impact or exercise habits, whereas the latter introduces novel items regarding footwear, orthopedics, assumptions about the disease and foot self-care habits. This combination of varied items allows the clinician to detect the main flaws of DFD patients to begin an individualized program towards prevention strategies.

Table 4
Correlation between the DiaFootQ questionnaire and the selected instruments for criteria validity analysis.

		DiaFootQ Total	DiaFootQ Factor 1	DiaFootQ Factor 2
SF−12	Physical Function	0.593	0.486	0.155
	Physical Role	0.479	0.388	0.196
	Bodily Pain	0.470	0.411	0.166
	General Health	0.386	0.291	0.154
	Vitality	0.590	0.583	0.145
	Social Functioning	0.459	0.359	0.170
	Emotional Role	0.599	0.529	0.125
	Mental Health	0.541	0.443	0.196
	Physical Component State	0.684	0.530	0.250
	Mental Component State	0.729	0.632	0.238
EuroQol VAS		0878	0.736	0.278
EuroQol 5D		0888	0.745	0.279
DQoL		0792	0.671	0.196
FFI	Index	−0.847	0.705	0.284
	Pain	−0.775	0.665	0.207
	Disability	−0.801	0.696	0.225
	Limit Activity	−0.845	0.704	0.270

4.1. Comparison with the existing literature

Nowadays, the assessment of patients with DFD presents significant challenges. Despite the existence of numerous objective-reported instruments, there are very few PROMs specifically designed for and applicable to this population [31]. The majority of classifications, scales and even questionnaires aim at such an important matter as diabetic foot ulcers, which directly implies the occurrence of amputations. However, this questionnaire merged from the importance of contextualizing each case, since two identical cases in different patients might not have the same chances of success [32]. In a recent systematic review [11], 12 valid and reliable PROMs were identified for use in the DFD population. Among these, two were highlighted: the Questionnaire for Diabetes Related Foot Disease (Q-DFD) [33] and the Diabetic Foot Self-Care Questionnaire (DFSQ-UMA) [34]. The Q-DFD assesses the presence of neuropathy and peripheral arterial disease by utilizing self-reported symptoms, foot ulceration, amputation, and deformity. On the other hand, the DFSQ-UMA focuses on DFD patient self-care. However, the authors did not recommend their individual use and suggested their combination.

In another related study [31], researchers identified 11 PROMs available for use in the DFD population, with particular emphasis on the Foot Health Status Questionnaire (FHSQ) [35]. While the FHSQ is known for its versatility, considering various aspects of foot health, it is essential to note that it was not developed specifically for a diabetic/DFD sample. Consequently, it lacks certain features, such as self-care and diabetes education. Additionally, the FHSQ comprises over 40 individual questions, making it a time-consuming PROM to administer. The development of a new instrument resulted from the detection of certain lacks in the existing PROMs, such as information about foot function, footwear, disability and the impact in patients' daily routine caused by DFD. These variables have been reported in previous studies as a main concern for patients, thus DiaFootQ allows clinicians to reflect this information in a structured questionnaire instead of keeping these meaningful data as part of their patients' history [36,37].

4.2. Psychometric characteristics of the DiaFootQ

The structural and psychometric characteristics of the DiaFootQ were compared with those of other questionnaires aimed at evaluating different aspects related to the diabetic foot (ulcers, self-care, among others). It was observed that, from a structural point of view, the number of items that make up the DiaFootQ was in medium ranges (25 items), while other questionnaires presented a number of questions that range between 7 items (Diabetes Foot Self-Care Behavior Scale; DFSBS) [38] and 58 items (Diabetic Foot Ulcer Scale; DFS) [39]. Furthermore, the Likert scale used has a score that ranges between 0 and 4, for a total score of 100. This structuring and evaluation system reduces, on the one hand, the time required to complete the questionnaire, and, on the other hand, the time required to calculate the score, thus facilitating its use in both clinical and scientific settings.

Furthermore, when analyzing the psychometric characteristics of the DiaFootQ, it was observed that it has an excellent interclass correlation index (ICC: 0.862 – 0.998), comparable to those observed in DFSCBS [38] (ICC=0.92) and DFSQ-UMA [34] (ICC: 0.89 – 0.92), and higher than those obtained in DFS-SF [40] and DFS [39], with ICC values: 0.54–0.77 and ICC:0.16 – 0.84, respectively. When analyzing the internal consistency through Cronbach's Alpha, excellent values were observed (0.916), comparable to those observed in DFS-SF (0.74 – 0.94), DFS [39] (0.22 – 0.95) and DFSQ-UMA [34] (0.89) and higher than that observed in DFSBS [38] (0.73). Regarding error measurements, DiaFootQ is the only tool that, in its original version, presents a calculation of both SEM and MDC, with values of 1.271 and 2.964, respectively.

4.3. Strengths and limitations

The lack of instruments designed explicitly for DFD patients is now addressed by developing a comprehensive PROM encompassing various aspects, including psychological and social impact, pain, physical impairments related to the feet, cultural considerations, patient habits and self-care. It demonstrated excellent reliability over time and very satisfactory correlations with other PROMs assessing foot function, quality of life, and diabetic foot self-care.

Furthermore, this PROM offers the advantage of being relatively time-efficient to complete, as it contains a reasonable number of questions (25 items) and 2 dimensions that are clearly defined. Additionally, its availability in the English language makes it suitable for implementation in both clinical practice and health research settings in most countries.

This questionnaire has been designed to evaluate subjective aspects of the patient with diabetic foot by analyzing clinical variables that have not been previously evaluated. Furthermore, the structure of the questionnaire has been developed to ensure that it is completed in reasonable times and that the calculation of both the two subcategories and the total value can be established almost automatically. In this way, it can be used in a simple, reliable and valid way, in both clinical and research environments.

However, there are some aspects that must be taken into account when interpreting the results. Specifically, the limitations of our research are those inherent to a closed survey. However, we tried to minimize the impact by providing free text space, allowing the experts to make any appropriate comments. In addition, the voluntary participation of the experts and the appropriateness of the sampling procedure used could also be considered a methodological limit. Either or both factors may have introduced a selection bias.

On the other hand, the initial response rate from the experts may have been determined by the communication channel used. Contacts were made through the public data of these experts. If this communication error occurred, it could also be considered a selection bias. Another possible limitation of the study may be that DFD patients were not included as part of the expert panel.

5. Conclusions

The DiaFootQ questionnaire is a well-structured, valid and reliable tool whose use should be promoted in clinical and research settings. The Delphi panel allowed developing a consensual tool integrating the main aspects that, according to the experts, should be considered when assessing and monitoring patients with DFD.

Ethical approval

This study involving human subjects was conducted in strict accordance with the ethical principles outlined in The Code of Ethics of the World Medical Association (Declaration of Helsinki) for experiments involving humans. The research protocol was reviewed and approved by the University of Malta on 26/03/2020, with reference number 4113.

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CRediT authorship contribution statement

María Ruiz-Muñoz: Conceptualization, Validation, Resources, Data curation, Project administration. **Raúl Fernández-Torres:** Software, Validation, Investigation, Writing – original draft, Visualization. **Cynthia Formosa:**Formal analysis, Writing – review & editing, Project administration, Funding acquisition. **Alfred Gatt:** Formal analysis, Writing – review & editing, Supervision. **Alberto José Pérez-Panero:** Investigation, Writing – original draft. **Ana Juana Pérez-Belloso:** Investigation, Data curation, Visualization. **Francisco Javier Martínez-Barrio:** Software, Project administration. **Manuel González-Sánchez:** Conceptualization, Methodology, Resources, Writing – original draft. All authors have read and agreed to the published version of the manuscript.

Declaration of Competing Interest

All authors declare that they have no conflict of interests.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.pcd.2024.07.002.

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