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Translation and validation of the Persian version of diabetic foot ulcer scaleshort form (DFS-SF)

Sedigheh Sadat Tavassolmand[1] | **Ali Montazeri**[2] | **Farzan Madadizadeh**[3] | **Hamid Reza Dehghan**[1] | **Mohammad Ranjbar**[4] | **Hosein Ameri**[4]

[1]Department of Health Technology Assessment, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

[2]Population Health Research Group, Health Metrics Research Center, Iranian Institute for Health Sciences Research, Tehran, Iran

[3]Center for Healthcare Data Modeling, Departments of Biostatistics and Epidemiology, School of Public Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

[4]Health Policy and Management Research Center, Department of health management and Economics, School of Public Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

Correspondence
Hosein Ameri, PhD, Health Policy and Management Research Center, Department of Health Management and Economics, School of Public Health, Shahid Sadoughi University of Medical Sciences, Yazd, Iran.
Email: hamery7@yahoo.com

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Abstract

Foot ulcer in diabetic patients could often result in significantly impaired quality of life. This study aimed to translate and validate the DFS-SF in Iran. The DFS-SF was translated into Persian, and then its validity and reliability were tested in 262 patients with DFUs. Content validity was evaluated using content validity ratio (CVR) and content validity index (CVI), and criterion validity was assessed through Spearman's correlation between dimensions of the DFS-SF and the EQ-5D-5L. Construct validity was measured using exploratory factor analysis (EFA) and confirmatory factor analysis (CFA), and convergent-discriminant validity was examined by calculating the average variance extracted (AVE) and composite reliability (CR). Cronbach's alpha and intraclass correlation coefficient (ICC) were calculated to evaluate the reliability of the measure. CVR $\geq$0.66 and CVI = 0.81 were calculated. Spearman's correlation ranged from 0.23 to 0.78 across all dimensions. The results of EFA showed that all six dimensions of the DFS-SF had an eigenvalue more than 1; accounting for 68.88% of the total variance. CFA confirmed the DFS-SF as a six-dimension structure with good fit indices of $\chi 2/df = 2.15 < 5$, RMSEA = 0.06 < 0.08, CFI = 0.91 $\geq$ 0.90, TLI = 0.90 $\geq$ 0.90, and RMR = 0.04, as well as with adequate fit indices of GFI = 0.84 $\leq$ 0.90, NFI = 0.86 $\leq$ 0.90. Estimates of $\geq$0.50 for AVE were not observed in two of the six dimensions and CR $\geq$0.70 was obtained for all dimensions. The reliability was calculated with a Cronbach's alpha of 0.89 and ICC >0.69 for all dimensions. Our findings confirmed the validity and reliability of the Persian DFS-SF; therefore, it can be used to assess QoL in patients with DFSs in clinical and research settings in Iran.

KEYWORDS

diabetic foot ulcer, Iran, quality of life, reliability, validity

Key Messages

- the quality of life (QoL) is one of the most commonly used outcomes for assessing interventions

- the Diabetic Foot Ulcer Scale Short Form (DFS-SF) provides adequate data for assessing QoL in the patients with DFUs
- the validity and reliability of the Persian DFS-SF were confirmed; therefore, it can be used to assess QoL in the patients with DFSs in the clinical and research settings

1 | INTRODUCTION

Diabetic Foot Ulcers (DFUs) are one of the most common and costly complications in the patients with diabetes mellitus (DM). DFUs have a progressive prevalence rate in developing countries compared with developed countries among diabetes mellitus patients. The world prevalence of DFUs is almost 6.4%, while its prevalence in Iran is as high as 8.1%.[1] The complication is caused by peripheral neuropathy and peripheral vascular disorders and occurs during the course of 15% to 25% of the patients with type 2 diabetes mellitus (T2DM).[1,2] Among patients diagnosed with DFUs, 61% of them became infected and about 15% of DFU patients had lower extremity amputation.[3] Foot ulcers are associated with significant morbidity that decrease health-related quality of life (HRQoL) in the patients. A systematic review showed that HRQoL in the patients with DFUs was lower than that in patients without DFUs.[4] The recent studies also supported poor HRQoL among people with DFUs compared with people without DFUs.[2,5,6]

DFUs not only significantly decrease HRQoL among patients but also impose a large economic burden on patients and the health care system of many countries. DFUs are the main reason for hospitalizations of the patients with T2DM compared with other complication of diabetes and impose $9 to $13 billion on the patients in addition to the costs related to diabetes itself.[7] However, evidence has shown that health expenditures are five times more in the patients with foot ulcers compared with patients without foot ulcers.[8] In Iran in 2009, of US$1 billion of diabetes complications expenditures, US$107 m (10.7%) was because of DFUs that was equivalent to 0.39% of total Iranian health expenditure and 0.02% of Iranian GDP.[9]

A significant economic burden along with decreased HRQoL in patients with DFUs make it necessary to assess interventions that are used to improve quality of life (QoL) in the patients. To do so, generic or disease-specific instruments have been designed. Disease-specific instruments in comparison with generic instruments include more clinical aspects of disease and are more sensitive to changes related to the disease. Diabetic Foot Ulcer Scale-Short Form (DFS-SF) is a DFUs-specific instrument commonly used for measuring QoL.[10] This instrument has been shown to be highly sensitive to ulcer severity, with few confounders.[11] However, some countries such as Korea, Spain, Brazil, and Turkey have introduced this instrument as an appropriate instrument for assessing QoL in the patients with DFUs, and have validated it.[12-15] However, no study has ever been validated this instrument for Iranian patients. Thereafter, this study aimed to translate the DFS-SF into Persian language and assess the validity and reliability of the Persian version of DFS-SF in a population of patients with DFUs in Iran.

2 | METHODS

2.1 | Study design and data collection

Assuming minimum acceptable Cronbach's alpha (H0) = 0.85, expected Cronbach's alpha (H1) = 0.80, $\alpha = 0.05$, $1\text{-}\beta = 0.90$, and number of items (k) = 29,[16] a total of 265 outpatients with DFUs were selected from the Diabetes Research Center and Clinics in Yazd through a consecutive sampling method. Yazd, a world heritage city, has the highest prevalence of DM based on HbA1c among cities of Iran, and its centre is one of the largest centres that provides specialised services for more than 10 000 diabetic patients.[2]

The DFS-SF and EQ-5D-5L instruments were filled out by patients through face-to-face interview during a single visit between September and December 2021. Clinical data were extracted from the medical records of patients. Patients included those who were able to speak and clinically confirm having DFUs, and all patients completed written informed consent. The present study was approved by the IR.SSU.SPH.REC.1399.200 Ethics Committee.

2.2 | Instruments

2.2.1 | Diabetic foot ulcer scale short form

The DFS-SF is the shortened version of the DFS commonly used to assess QoL in the patients with DFUs. DFS-SF consists of 29 items ranging from 1 "not at all" or "none of the time" to 5 "a great deal" or "all of the time" or "extremely". The items are grouped into six domains as follows: leisure(Lsr) (5 items), physical health (Phy) (5 items), dependence/daily life (Dpn)(5 items), negative emotions (NgE)(6 items), worried about ulcers/ft (Wrr)

(4 items) and bothered by ulcer care (Bth)(4 items). The score of each DFS-SF dimension is calculated by the sum of all the items in each domain. Score of the DFS dimensions is ranged from 0 to 100, higher scores reflect better QoL. The validity and reliability of the original English version of the instrument were confirmed.[10]

2.2.2 | EQ-5D-5L

The EuroQol 5 dimensions instrument (EQ-5D), which was developed by the EuroQol group, is the most common form of preference-based instruments for assessing HRQoL. The EQ-5D may be used in two versions: the EQ-5D-3L and EQ-5D-5L. Previous evidence has shown that the performance of EQ-5D-5L in ceiling effects, discriminant activity, and sensitivity to health changes was better than EQ-5D-3L.[17] EQ-5D-5L describes health by a classification system of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each EQ-5D-5L dimension is rated on a 5-point Likert-type scale: no problems, slight problems, moderate problems, severe problems and extreme problems. The EQ-5D-5L value varies between less than 0 (worse than dead) to 1 (perfect health). This questionnaire has been translated into Persian language, and confirmed by the EuroQol group.[18]

2.3 | Translation and cross-cultural adaptation

The process of questionnaire translation was conducted in accordance with the guidelines of MAPI Research Institute. First, the English original version was translated word-for-word into Persian language by two independent bilingual translators, one of them was familiar with the terms of medical sciences and diabetes, and another was not. Then, the two translations were compared by a third translator, who was expert in both languages, and provided a common forward translated version. After this, the first Persian version was back-translated by two translators without referring to the original version. Then, the two backward translations were compared by the third translator, and a reconciled Persian version of DFS-SF was produced and compared with the original version.

2.4 | Validity and reliability

Content validity was assessed through the content validity index (CVI) and the content validity ratio (CVR) by an expert panel of 4 wound specialist nurses, 4 doctors, 2 epidemiologists, and 2 health economists. The experts were asked to independently rate each of questions into one of the following three categories: "essential," "useful, but not essential," or "not necessary" according to the criteria introduced by Lawshe. The CVR for each question was computed based on Lawshe's formula CVR = (ne – N/2)/N/2, where N is the number of experts and ne is the number of experts who report an item as "essential". The CVR values based on the number of experts ranged from −1 to +1. According to the Lawch's table for 12 experts, the CVR values higher than 0.56 were acceptable.

TABLE 1 Demographic and clinical characteristics of the patients

Characteristic	First survey (262) N (%)	Resurvey(27) N (%)
Gender		
Male	153(58.40)	17(62.96)
Female	109(41.60)	10(61.96)
Age group, y		
≤39	50(19.08)	4(14.81)
40–49	88(33.59)	13(48.15)
50–59	73(27.86)	9(33.33)
≥60	51(19.47)	1(3.70)
Education status		
Primary	44(16.79)	9(33.33)
Secondary	130(49.62)	14(51.85)
University degree	85(33.59)	4(14.82)
Marital status		
Married	202(77.10)	25(92.5)
Divorced or widow	49(18.70)	2(7.5)
Single	11(4.2)	-
Current treatment status		
Oral therapy only	113(43.13)	12(44.44)
Insulin alone or combined	149(56.87)	15(56.56)
Location		
Forefoot	84(20.61)	11(40.74)
Midfoot	73(28.10)	8(29.63)
Hindfoot	69(26.10)	5(18.52)
Ankle or above	66(25.20)	3(11.11)
Wagner stage classification		
Grade 1	70(26.72)	7(25.93)
Grade 2	77(29.39)	11(40.74)
Grade 3	72(27.48)	5(18.52)
Grade 4	40(15.27)	4(14.82)
Grade 5	3(1.15)	-

TABLE 2 Factor loading from exploratory factor analysis for DFS-SF

		Factors					
Item no.	**Description**	**Lsr**	**Phy**	**Dpn**	**NgE**	**Wrr**	**Bth**
Q1A	Stopped from engaging in recreational activities	0.758	0.139	0.225	0.089	0.115	0.209
Q1B	Changed kinds of recreational activities	0.799	0.180	0.135	0.184	0.167	0.075
Q1C	Stopped from getting away for a holiday	0.801	0.127	0.208	0.069	0.070	0.060
Q1D	Made you choose different kind of holiday	0.788	0.192	0.087	0.140	0.074	0.007
Q1E	Had to spend more time planning leisure activities	0.690	0.133	0.158	0.189	0.121	0.128
Q2A	Felt fatigued	0.314	0.263	0.488	0.219	0.128	0.358
Q2B	Felt drained	0.357	0.110	0.588	0.110	0.161	0.377
Q2C	Had difficulty sleeping	0.221	0.210	0.766	0.086	0.008	0.131
Q2D	Pain while walking or standing	0.312	0.284	0.685	0.130	0.068	0.017
Q2A	Pain during night	0.239	0.177	0.593	0.397	0.093	0.033
Q3B	Depend on others to look after you	0.694	0.112	0.292	0.079	0.053	0.355
Q3C	Depend on others to do household chores	0.693	0.135	0.283	0.111	0.052	0.474
Q3D	Depend on others to get out of the house	0.682	0.170	0.173	0.113	0.023	0.464
Q3E	Spend more time planning daily life	0.518	0.200	0.162	0.059	0.107	0.572
Q3F	Felt doing anything took longer than would have liked	0.397	0.130	0.166	0.227	0.155	0.494
Q4A	Angry because you are not able to do what you wanted	0.192	0.218	0.160	0.739	0.154	0.038
Q4B	Frustrated by others doing things for you	0.130	0.157	0.131	0.848	0.115	0.170
Q4C	Frustrated because you are not able to do what you wanted	0.207	0.367	0.175	0.664	0.099	0.027
Q4G	Depressed because you are not able to do what you wanted	0.178	0.585	0.096	0.321	0.135	0.297
Q4I	Angry that this has happened to you	0.029	0.711	0.191	0.035	0.308	0.196
Q4J	Frustrated because you have difficulty getting around	0.107	0.528	0.236	0.201	0.287	0.339
Q5D	Worried that ulcer will never heal	0.245	0.688	0.209	0.148	0.018	0.296
Q5E	Worried that you may have to have an amputation	0.232	0.705	0.208	0.307	0.084	0.068
Q5F	Worried about injury to feet	0.184	0.592	0.051	0.372	0.044	0.188
Q5H	Worried about getting ulcers in future	0.166	0.702	0.138	0.045	0.206	0.139
Q5A	Bothered by having to keep weight of foot ulcer	0.063	0.193	0.054	0.179	0.676	0.233
Q5B	Bothered by amount of time involved in caring for ulcer	0.304	0.074	0.034	0.104	0.822	0.044
Q5C	Bothered by appearance of ulcer	0.307	0.181	0.306	0.055	0.682	0.016
Q5D	Bothered by having to depend on others for care of ulcer	0.623	0.107	0.201	0.188	0.357	0.274
Eigenvalues		12.05	2.98	1.56	1.23	1.30	1.02
Variance (%)		18.14	14.80	10.53	9.28	8.63	7.50
Accumulation (%)		18.14	32.90	43.47	52.75	61.38	68.88

Abbreviations: Bth, bothered by ulcer care; Dpn, dependence/daily life; Lsr, leisure; NgE, negative emotion; Phy, physical health; Wrr, worried about ulcers/ft.

The CVI was also calculated based on Lawshe's method as average of the CVR values of number of the retained questions.[19] The CVI values range from 0 to 1, where CVI > 0.79, the questions are relevant and accepted, 0.70 < CVI < 0.79, the questions need revisions, and CVI < 0.70 the questions are eliminated.[20]

Construct validity was first assessed using exploratory factor analysis (EFA) and then the results were verified through confirmatory factor analysis (CFA). Before performing EFA, the sampling adequacy and suitability of the data for factor analysis were determined by running the Kaiser-Meyer-Olkin (KMO) test and Bartlett's sphericity test. KMO value is ranged from 0 to 1, when KMO is ≥0.80 and the Bartlett's test is $P < 0.05$, data are suitable for factor analysis. The EFA was performed by principal axis factoring extraction method and varimax

rotation. Factor loading values ≥0.3 were considered as an important relationship between items and factors.

The confirmatory factor analysis was conducted to assess how well the elementary factors produced by the EFA using the ratio of chi square to its degrees of freedom ($\chi 2/df$), comparative fit index (CFI), Tucker-Lewis index (TLI), goodness of fit index (GFI), normed fit index(NFI), root mean square residual(RMR) and root mean square error of approximation (RMSEA). In addition, convergent-discriminant validity was conducted.

Convergent validity was performed to test the degree of inter-relation for the items of the same dimension that are in agreement. Convergent validity was examined by calculating the average variance extracted (AVE) and composite reliability (CR), AVE values ≥0.50 and CR ≥0.70 were considered as an adequate convergent validity.[21] Discriminant validity was assessed to determine whether questions of one dimension have a strong correlation with another dimension. According to Fomell and Larcker, there is an adequate discriminant validity between dimensions i and j if the root square of AVEij is greater than the correlation between the dimensions i and j (ρij).[22]

Criterion validity was measured through spearman's correlation between dimensions of the DFS-SF and the EQ-5D-5L. The EQ-5D-5L is commonly used to assess QoL and its validity and reliability have been internationally proven.

2.5 | Reliability

The reliability of the DFS-SF was evaluated based on internal and external reliability. Internal reliability was checked with Cronbach's alpha (α), $\alpha < 0.70$ was poor, $0.70 < \alpha < 0.90$ was good, and $\alpha > 0.90$ was an excellent internal consistency. External reliability was assessed using the intraclass correlation coefficient (ICC) obtained from the data of a sub-sample of 110 patients who were resurveyed after 3 weeks of the first survey. The ICC was considered as poor (<0.40), fair to good (0.40–0.75), and excellent (> 0.75). The data were analysed with SPSS 22 and Amos 22 software.

3 | RESULTS

After removing three participants of first survey because of missing more than 50% of the responses on some of the DFS-SF dimensions, data of 262 patients included in final analysis. Table 1 presents the results of descriptive statistics for demographic and clinical characteristics of two surveys. Out of 30 patients who were resurveyed, three cases were excluded because their general health status had changed during the interval between two surveys. As shown in the two surveys, the majority of patients were male, married, in the age group of 40–49 years, and secondary educated. More than half of patients received both Insulin alone or in combination with pill, and the majority of patients had forefoot ulcers and were diagnosed with grade 2.

3.1 | Content validity

The value of CVR for all questions was more than 0.66. Among the 29 questions, the CVR for 11 questions was 0.66, for 10 questions was 0.83, and for 8 questions was 1. The CVI was 0.81 for all questions.

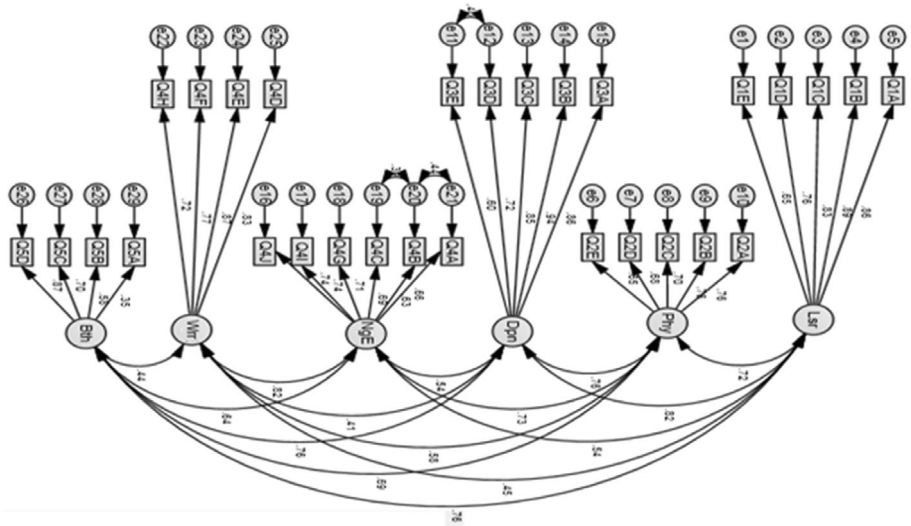

FIGURE 1 Confirmatory factor analysis. Lsr, leisure; Phy, physical health; Dpn, dependence/daily life; NgE, negative emotion; Wrr, worried about ulcers/ft; Bth, bothered by ulcer care

TABLE 3 Convergent validity of DFS-SF

	Standardised estimate	Estimate	S.E.	C.R.	*P*	C.R.	AVE
Q1E ← Lsr	0.647	1.000					
Q1D ← Lsr	0.757	1.208	0.114	10.597	<0.001	0.898	0.641
Q1C ← Lsr	0.828	1.602	0.141	11.369	<0.001		
Q1B ← Lsr	0.888	1.717	0.143	11.977	<0.001		
Q1A ← Lsr	0.859	1.534	0.131	11.698	<0.001		
Q2E ← Phy	0.648	1.000					
Q2D ← Phy	0.682	0.887	0.094	9.393	<0.001	0.835	0.504
Q2C ← Phy	0.695	1.045	0.110	9.535	<0.001		
Q2B ← Phy	0.761	1.252	0.122	10.233	<0.001		
Q2A ← Phy	0.757	0.953	0.094	10.192	<0.001		
Q3E ← Dpn	0.595	1.000					
Q3D ← Dpn	0.721	1.008	0.084	11.972	<0.001	0.899	0.646
Q3C ← Dpn	0.855	1.603	0.152	10.551	<0.001		
Q3B ← Dpn	0.940	1.617	0.145	11.120	<0.001		
Q3A ← Dpn	0.860	1.482	0.140	10.592	<0.001		
Q4J ← Wrr	0.740	1.000					
Q4I ← Wrr	0.744	0.951	0.082	11.634	<0.001	0.850	0.487
Q4G ← Wrr	0.714	0.951	0.085	11.151	<0.001		
Q4C ← Wrr	0.690	0.997	0.093	10.761	<0.001		
Q4B ← Wrr	0.635	0.883	0.090	9.839	<0.001		
Q4A ← Wrr	0.657	0.986	0.096	10.228	<0.001		
Q4H ← NgE	0.724	1.000					
Q4F ← NgE	0.772	1.081	0.090	11.955	<0.001	0.876	0.639
Q4E ← NgE	0.865	1.277	0.096	13.324	<0.001		
Q4D ← NgE	0.826	1.210	0.095	12.776	<0.001		
Q5D ← Bth	0.866	1.000					
Q5C ← Bth	0.705	0.627	0.052	11.963	<0.001	0.732	0.426
Q5B ← Bth	0.578	0.435	0.046	9.446	<0.001		
Q5A ← Bth	0.352	0.310	0.057	5.452	<0.001		

Abbreviations: Bth, bothered by ulcer care; Dpn, dependence/daily life; Lsr, leisure; NgE, negative emotion; Phy, physical health; Wrr, worried about ulcers/ft.

TABLE 4 Discriminant validity of DFS-SF

	Lsr	Phy	Dpn	NgE	Wrr	Bth
Lsr	0.800					
Phy	0.717	0.710				
Dpn	0.822	0.760	0.804			
NgE	0.542	0.732	0.538	0.799		
Wrr	0.452	0.580	0.413	0.820	0.699	
Bth	0.760	0.693	0.763	0.637	0.439	0.653

Abbreviations: Bth, bothered by ulcer care; Dpn, dependence/daily life; Lsr, leisure; NgE, negative emotion; Phy, physical health; Wrr, worried about ulcers/ft.

3.2 | Construct validity

KMO measure of the sampling adequacy was 0.90, higher than the good level of 0.80. The Bartlett sphericity test was significant (*P*-value <0.001), the chi-square value and degree of freedom were 4926.409 and 406, respectively. Therefore, the results of the KMO measure and the Bartlett sphericity test verified the adequacy of the data and samples for factor analysis.

The results of EFA showed that six factors had an eigenvalue more than 1; accounting for 68.88% of the total variance (Table 2). The Lsr had an eigenvalue of 12.05 and explained 18.14% of the total variance; the Phy

TABLE 5 Criterion validity of DFS-SF

EQ-5D-5L dimensions	DFS-SF dimensions					
	Lsr	Phy	Dpn	NgE	Wrr	Bth
Mobility	−0.730**	−0.579**	−0.785**	−0.439**	−0.365**	−0.470**
Self-care	−0.691**	−0.516**	−.0753**	−0.418**	−0.287**	−0.484**
Usual activities	−0.661**	−0.535**	−0.699**	−0.463**	−0.327**	−0.446**
Pain/discomfort	−0.652**	−0.663**	−0.694**	−0.562**	−0.233*	−0.483**
Anxiety/depression	−0.303**	−0.384**	−0.402**	−0.280**	−0.483**	−0.229**

Note: ** Significant at the 0.01 level. * Significant at the 0.05 level.
Abbreviations: Bth, bothered by ulcer care; Dpn, dependence/daily life; Lsr, leisure; NgE, negative emotion; Phy, physical health; Wrr, worried about ulcers/ft.

TABLE 6 Internal and external consistency reliability of the DFS-SF

	Average inter-item correlation[a]	Cronbach's alpha	(ICC [95%CI])
Lsr	0.80	0.90	0.88(0.70-0.95)
Phy	0.65	0.83	0.79(0.50-0.91)
Dpn	0.66	0.89	0.79(0.50-0.91)
NgE	0.53	0.86	0.69(0.23-0.87)
Wrr	0.64	0.87	0.77(0.45-0.90)
Bth	0.77	0.75	0.84(0.60-0.94)

Abbreviations: Bth, bothered by ulcer care; Dpn, dependence/daily life; Lsr, leisure; NgE, negative emotion; Phy, physical health; Wrr, worried about ulcers/ft.
[a]Spearman's correlations.

had an eigenvalue of 2.98 and explained 14.8% of the total variance; the Dpn had an eigenvalue of 1.56 and explained 10.53% of the total variance; the NgE had an eigenvalue of 1.23 and explained 9.28% of the total variance; the Wrr had an eigenvalue of 1.30 and explained 8.63% of the total variance; and the Bth had an eigenvalue of 1.02 and explained 7.50% of the total variance.

Confirmatory factor analysis showed that the six-factor structure of the DFS-SF was appropriate. Good fit indices were as follows: $\chi 2/df = 2.15 < 5$, RMSEA $= 0.06 < 0.08$, CFI $= 0.91 \geq 0.90$, TLI $= 0.90 \geq 0.90$, RMR $= 0.04$, GFI $= 0.84 \leq 0.90$, and NFI $= 0.86 \leq 0.90$. In addition, factor loadings of questions ranged from 0.35 to 0.94, and those of six factors were between 0.41 and 0.82. All factor lodgings of 29 questions on six factors were statistically significant ($P < 001$) (Figure 1).

3.3 | Convergent validity

The results of convergent validity showed that AVE values ranged from 0.426 for those bothered by ulcer care dimension to 0.646 for the dependence/daily life dimension. The values of CR were between 0.732 for those bothered by ulcer care dimension and 0.898 for leisure dimension (Table 3).

Square root values of AVE reported on the diagonal line were as follows: lsr, 0.80; Phy,0.71; Dpn, 0.80; NgE,0.80; Wrr, 0.70; and Bth, 0.65 (Table 4). As shown in Table 4, the square root of AVE for each of the dimension of DFS-SF is less than its correlation with other dimensions in its row and column.

3.4 | Criterion validity

Spearman's correlation between dimensions of the EQ-5D-5L and DFS-SF is presented in Table 5. The correlation between dimensions ranged from 0.229 for the Bth and anxiety/depression to 0.785 for the Dpn and mobility (Table 5).

3.5 | Reliability

Spearman's correlation between each dimension of DFS-SF in two surveys varied from 0.53 (NgE) to 0.80 (Lsr). The Cronbach's alpha for all the DFS-SF questions was 0.89, while that varied among dimensions from 0.75 (Bth) to 0.90 (Lsr). The ICC of dimensions was between 0.69 of NgE and 0.88 of Lsr (Table 6).

4 | DISCUSSION

This study was conducted to adapt the DFS-SF instrument for Iranian culture and to examineits criterion, content, convergent, discriminant, and construct validity, and reliability in a population of the patients with DFUs in Iran.

The results of content validity (ie, CVR and CVI) showed that the Persian DFS-SF represents all facets of a given construct. The value of CVR for each of the questions was more than 0.66, therefore, those were higher than the accepted level of 0.56 based on the Lawch's Table for 12 experts. The CVI was 0.81 for all questions, which was higher than an excellent level of 0.80 CVI.[20] Content validity of the DFS-SF was also confirmed in the studies conducted in Korea with 0.98 CVI and Turkey with 0.97 CVI. Although our CVI was higher than the cut-off for an excellent level in CVI, the value of CVI in the present study was lower than that in studies in Korea[14] and Turkey.[15] This difference can be because of differences in the number of experts and their expertise. In our study, there were 12 experts from four different medical groups while studies in Korea and Turkey had 6 and 9 experts, respectively, and were from a medical group.

The findings of the explanatory factor analysis showed that the six factors of the Persian DFS-SF explained 69% of the total variance. The explanatory power of 69% was higher than the cut-off of 50%, which is adequate and acceptable for the factors structure.[23] This result supports the six -factor structure of the DFS-SF and is in line with the findings of the EFA reported in Korea and Turkey. Also in the present study, the results of CFA, which used explanatory factor analysis in verifying construct validity, confirmed the DFS-SF as a six-factor structure with good fit indices of $\chi 2/df = 2.15 < 5$, $RMSEA = 0.06 < 0.08$, $CFI = 0.91 \geq 0.90$, $TLI = 0.90 \geq 0.90$ and $RMR = 0.04$, as well as adequate fit indices of $GFI = 0.84 \leq 0.90$, $NFI = 0.86 \leq 0.90$. When comparing the good fit indices in the present study with $\chi 2/df = 4.64$, $CFI = 0.92$, $TLI = 0.91$, $GFI = 0.73$, $NFI = 0.90$, $RMR = 0.06$ and $RMSE = 0.1$ in Korea,[14] and with $CFI = 0.84$, $RMR = 0.093$, and $RMSE = 0.095$ in Spain,[12] the findings of the two studies of Iran and Korea were consistent and better than those in Spain. The better performance of the CFA in Iran and Korea compared xwith the CFA in Spain could be attributed to the greater number of sample size in the studies of Iran (262) and Korea (320) compared with that in Spain (141). Standardised factor loadings also confirmed the original structure so that each of the six factors was well defined by its items with factor loadings >0.30.

Convergent validity was examined using the AVE and CR in this study. The results of AVE showed that all dimensions of DFS-SF were over 0.5, except for two dimensions of Bth (0.43) and Wrr (0.49) which were close to the threshold value of 0.5. The values of CR for all dimensions were over than an accepted level of 0.70 CR. Nevertheless, AVE ≥0.50 and convergent validity were not observed for the two dimensions of DFS-SF. In addition, discriminate validity was not achieved for any dimension in this study. The findings were not consistent with those in the only study (Korea's study) that used AVE and CR to assess convergent validity of DFS-SF. The study conducted in Korea confirmed convergent-discriminate validity of the instrument.[14] This difference can be explained by sample size in two studies. Sample size in Korea was larger than that in Iran. When assessing convergent and discriminant validity through Spearman's correlation between dimensions of the DFS-SF and the EQ-5D-5L in this study, the degree of correlation between the DFS-SF dimensions that are theoretically very similar to the EQ-5D-5L dimensions is higher than correlations of the DFS-SF and EQ-5D-5L dimensions which are theoretically dissimilar (eg, Dpn of the DFS-SF had a better correlation with mobility than with anxiety of the EQ-5D-5L) (Table 3). Moreover, the convergent and discriminant validity was not reported by other studies using AVE and CR. It is needed to assess AVE and CR in future studies.

High and significant correlations between dimensions of the Persian DFS-SF and EQ-5D-5L demonstrated good criterion validity for the DFS-SF. This finding is similar to the finding of another study that used EQ-5D-5L as a valid instrument to verify criterion validity.[12]

Internal consistency was confirmed for the Persian DFS-SF with good Cronbach's alpha value of 0.89. Our finding is consistent with Cronbach's alpha values calculated in Korea (0.95), Turkey (0.94), Greek (0.94), and China (0.90).[14,15,24,25] The ICC values of dimensions were between 0.69 and 0.88, which demonstrated good-excellent external consistency. Our findings were consistent with the ICC ranged from good to excellent (0.77-0.92) for the Spanish DFS-SF, the only study assessing external consistency of the DFS-SF.[12] The ICC values for the Spanish DFS-SF were higher than those of our study. This may be because of the difference in the time interval considered between initial and repeated survey to perform test–retest. This interval in Spanish study (1 week) was fewer than that of our study (3 weeks).[12]

The major limitation of this study was the selection of only one centre for recruiting patients with DFUs. Although the centre was one of the largest academic centres for patients with diabetes in Iran that admits many patients from neighbouring provinces, those cannot be perfectly representative of other patients. This would affect the generalizability of the results of the present study. Another limitation is the use of convenience sampling method; it may be a limitation to generalising the results of this study.

5 | CONCLUSION

This is the first report of the validity and reliability of the Persian DFS-SF. The findings of content, criterion, and construct validity supported validity of the DFS-SF for use in Iran. The findings of convergent and discriminant validity using AVE and CR did not meet the validity criteria for the instrument, while the findings of Spearman's correlation between dimensions of the DFS-SF and the EQ-5D-5L confirmed convergent and discriminant validity. The values of Cronbach's alpha and ICC confirmed reliability of the Persian version of DFS-SF. Finally, this study enables researchers to use the Persian DFS-SF for assessing QoL of the patients.

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CONFLICT OF INTEREST

All the authors declare that they have no conflict of interest.

DATA AVAILABILITY STATEMENT

Data are available on reasonable request.

ORCID

Hosein Ameri https://orcid.org/0000-0002-9914-034X

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