




ORIGINAL ARTICLE

Transcultural adaptation and validation of Italian Selfcare diabetic foot questionnaire

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Abstract

The Italian Selfcare diabetic foot questionnaire, (SDFQ-IT) is considered a diabetic foot self-care evaluation tool with 16 questions for assessing diabetic foot health disorders. To date, SDFQ has been validated in different languages, but an Italian version was lacking. Consequently, the purpose of this study was to translate and validate the Italian version of the SDFQ-IT (SDFQ-IT). A suitable method was developed for the translation protocol and cross-cultural validation from Spanish to Italian. Regarding the total marks from each sub-scale, agreement degrees, and confidence were analysed using the Cronbach's α and intraclass correlation coefficient (ICC), respectively. In addition, the mean \pm SD differences between pre and post-tests were calculated and completed using the Bland and Altman distribution plots. Excellent agreement between the two versions based on Cronbach's α was demonstrated. Three sub-scales consisting of knowledge of foot hygiene, the appropriate use of footwear and socks, and podiatric self-care were added together to obtain the total score. Excellent retest reliability was shown for the total score. Test/retest reliability was excellent for the self-care domain, and shock and shoe sub-scales. There were no significant differences among any domain ($P > .05$). There were no statistically significant differences ($P = .000$) for the mean \pm SDs differences between pre-and post-tests (92.9200 ± 12.914) [89.25-96.59] and 92.9200 ± 13.012 [89.22-96.62] points, respectively). Bland and Altman plots or clinically pertinent variations were not statistically significantly different. The SDFQ-IT is considered a strong and valid questionnaire with adequate repeatability in the Italian community.

KEYWORDS

diabetic foot, questionnaire, self-care, self-management

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1 | INTRODUCTION

Questionnaires, such as the Achilles Tendon Total Rupture Score (ATRS), American Orthopaedic Foot and Ankle Society's (AOFAS), and foot function index (FFI) were adapted for use in Italian and verified for measuring the quality of an individual's foot life.¹⁻³

Diabetes mellitus (DM) prevalence in the western world ranges from 5% to 7% of the population, with an estimated 300 million people with diabetes by 2025.^{4,5} Complications of DM represent the main cause of morbidity and mortality among the diabetic population.⁶

Diabetic foot syndrome (DFS), affects 15% of diabetic patients throughout the evolution of their disease and it is the result of DM -induced neuropathy and vasculopathy in lower limbs,^{7,8} in some case, suppose a hospital admissions, and the loss of the limb,⁹ it represents near to half of non-traumatic lower extremity amputations especially in over 60 years patients, usually as a result of foot ulcers in 85% of these cases. Furthermore, the health-related quality of life (QoL) decreases. In fact, one-third of patients who had suffered from extremity amputation walk again using a prosthesis.^{9,10} The prognostic of amputation is bad, the mortality is 30% in the first year after surgery and after 5 years 50% suffer amputation of the other lower limb, DFS is not only an important factor of mortality also decreases QoL.^{11,12}

To estimate the impact of dangerous behaviour on the well-being of diabetic, researchers have developed self-care clinimetric instrument measures.

The Selfcare diabetic foot questionnaire (SDFQ) is a self-administered instrument with 16 items that measure knowledge of foot hygiene, the appropriate use of footwear and socks, and podiatric self-care. The SDFQ was developed in Spain with appropriate and concurrent validity in other countries.¹³

Nevertheless, the SDFQ was valeted with very good agreement in the French language.¹⁴

Care and management carried out by diabetic patients, is the most used psychological terms, owing to self-perception or habits on the ability to develop skills.¹³ Self-care of chronic process, for example, DM is an elemental piece of effectivity of holistic treatment. The goal of self-care in diabetic population management is to allow better education and recognise of complications involved in the diabetic disease. Diabetic foot self-care must be a daily routine, patients must develop this habit from the beginning of diabetic symptoms such as a right administration of the chronic process.¹⁵ It has been estimated that self-care conduct on diabetic subjects is one of the main aspects to take the control of basic pathology. The self-efficacy model has important results related to

Key Messages

- the Italian version of the Self-care diabetic foot questionnaire University of Málaga (SDFQ-UMA-IT) is a valid and reliable tool
- the SDFQ-UMA-IT provides practitioners to identify and classify diabetic foot risk in Italian -speaking patients. Therefore, it can be considered a useful psychometric tool
- extracting results from the SDFQ-UMA-IT, can be compared on diabetic patients who have completed the same tool but in other context due to the fact have been validated mother tongue, such as French or Spanish

self planification about benefits conduct.¹⁶ To educate on foot self-care in diabetic subjects to upgrade questions related to shoes, daily washing habits, or self-management so that complications involved to diabetic foot (eg, ulcers or infection) furthermore could improve QoL.¹⁷

Due to the fact that the presence of diabetic complications exists a need to develop a self-care tool to quantify self-administration on diabetic subjects because there are only a few studies on this field.^{14,18,19}

Relative to this aspect, carry out tolls with results reported by the patients themselves (Patient Reported Outcomes) (PRO) is an extended strategy, especially in case of chronic process.

PRO's inform about status health of subjects without clinicians interventions²⁰ to record aspects related to patients skill, and feelings and relationship with the pathology or treatment.²¹ It is supposed to be more than the evaluation of survivor of patients, the effectiveness treatment, or adverse events. This days are improving in the researches specially in pharmacological clinical trials, specially health-related quality of life (HRQL) the mainly tip, even though could be used in other topics like self-care, self-efficacy, etc.

Relative to the marks of diabetic self-care, several clinimetric tools has items related to measure variables about subject type (11.12), only a few are designed to evaluate foot self-care.²²⁻²⁴ Several health questionnaires present many different degree between them, high level of variability has presented relative to, that is, methodological aspect as a deficient samples size in this researches have limited the reproducibility in other populations, therefore, the comparison of the results are limited.²⁵⁻²⁷

Due to the fact the low degree of information, with based evidences results, to report people about diabetes on foot care.²⁸ Recently, have been developed specific Guidelines published by the American Diabetes Association (ADA) and the International Working Group on the Diabetic Foot, relative to this aspect.^{20,29}

Normally, diabetologic education related to foot care is developed in programmes for subjects who suffer DM complications, especially when HbA1c levels are not under control and patients with a long natural history evolution.³⁰ In fact, mostly researches have developed mainly on reduction of wounds and diabetic complications^{26,31-33} only a little of this is centred to establish the rank of self-care relative to foot condition in DM groups.^{30,34-37}

Therefore, subjects can be classified in a rapid manner as a low risk group for the development of secondary complications, however, without glycaemic control and foot self-care³⁰ should be taking into account and not only in patients with antecedents ulcer.

Moreover, some researches showed that women has poor levels of related Qol if they have foot disorders. As a consequence of sex condition could modify health status generating harmful on feet such as rheumatologic, diseases, and pregnancy so that, sometimes within DM or musculoskeletal disorders as the case of foot disorders.

Nevertheless, the fact of having information about foot self-care diabetic women, with regard of complications, the fact to intervene precocious in order to develop educational measures when the self-care was deficient. To complete this challenge, must use a reported tool by the patient, useful in clinical activities and with a high validity and reliability degree.

Consequently, the SDFQ reflects awareness of diabetic foot self-care in study subjects, and it can also be used to evaluate the post-interventional differences to determine the state of foot health within the population.^{17,19,38}

The main purpose of the research is the measurement of diabetic foot self-care population using a questionnaire, adapted to the Italian language the SDFQ as a valid measure.¹³

2 | MATERIAL AND METHODS

A cross-sectional descriptive study was conducted between May and November 2020 following the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE).³⁹ Translation and validation processes were developed using the SDFQ as a clinimetric instrument.¹³ The study was developed in Italy. We recruited the sample in medical centre, in Milano, Italy.

2.1 | Sample size calculation

To calculate the sample size, G*Power 3.1.9.2 software (Heinrich-Heine-Universität Düsseldorf; Düsseldorf, Germany) was used after considering to test the correlation between two paired means regarding correspondence with an spearman correlation coefficient of .40 and a 95% confidence interval (CI) for a two-tailed test, an error α of .05, a desired analysis power of 80% (error $\beta = 20\%$), a final sample size of 46 participants are needed.⁴⁰

The sample heterogeneity was tested for this tool for numerous and diverse foot statuses.⁴⁰

Ethical Committee was obtained from University of Valencia. In addition, all patients were informed of the study purpose, and their consent was obtained. Ethical standards were based on The Declaration of Helsinki.⁴¹

2.2 | Content validity

Was development qualitatively, the tool was completed by study subject and they were asked about of ambiguous item and identified it. Furthermore, a senior podiatry researcher were asked to review the Italian version of the clinimetric tool in terms of content.

2.3 | Statistical analysis

All variables were tested for normality of distribution using the Shapiro Wilks test, and data were considered normally distributed if $P > .05$.

Quantitative variables were expressed as mean \pm SD (IC95%). The sociodemographic characteristics as age, height, weight and Body Mass Index (BMI) were registered.

For parametric data independent t student or U Mann Whitney test for non-parametric data was be used to test differences between groups. Also, paired *t* test or Wilcoxon signed-rank test will be used for parametric and no parametric data, respectively for the purpose of testing systematic differences between test & retest.,

Regarding total score and each domain score, internal consistency and reliability were analysed using the Cronbach α . This parameter was used to summarise the internal correlations of all items on a scale.

For clarifying, a higher coefficient (which ranged from 0.0 to 1.0) was considered more consistent for the scale with a greater likelihood to reflect an underlying single variable on the questionnaire. We examined correlations of all items with the overall score and also whether Cronbach's was improved by removal of any item. We examined correlations of all items with the overall score using non-parametric spearman test or parametric Pearson test.

Independent Student *t* tests were calculated in order to find if differences were statistically significant when showing a normal distribution. Considering total score and each domain, reliability and internal consistency were analysed through intraclass correlation coefficient (ICC) and the Cronbach alpha (α) with a 95% confidence interval (95% CI), respectively. For the statistical analysis, a two-way random effects model (2.1), single measures, absolute agreement, and ICC were calculated to express concordance reliability between the test and retest. To interpret ICC values, we used benchmarks as proposed by Landis and Koch⁴² with <0.20 as slight agreement, 0.21 to 0.40 as fair, 0.41 to 0.60 as moderate, 0.61 to 0.80 as substantial, and >0.81 as almost perfect. Furthermore, Bland and Altman plots were calculated to evaluate agreement and heteroscedasticity.⁴³

Regarding each dimension score and total score, correlation and reliability and internal consistency, were analysed using Spearman (r_s), intraclass correlation coefficients [ICC] and the Cronbach's alpha, respectively. Cronbach's alpha was used to outline the internal consistency of whole questions on a dimension. To clear up, a major coefficient [oscillate, between 0.0 and 1.0] was contemplated more uniform for the domain with an excellent possibility to consider a supporting individual variable on the clinimetric instrument. Correlations of all questions were checked with the equally degree and also if Cronbach's alpha was removing. We tested correlations of all questions with the overall degree using non-parametric spearman test.

Internal consistency was assessed with Cronbach's alpha. Internal consistency above 0.7 is acceptable.

3 | RESULTS

All variables studied showed a no normal distribution ($P < .05$), except age, weight. Height and Body Mass Index (BMI) showing a normal distribution ($P > .05$).

The sociodemographic data are showed in Table 1.

The total data and all domains studied during the test and retest showed a non-normal distribution ($P < .05$), so the distribution was analysed using the non-parametric paired Wilcoxon signed-rank test in order to test systematic differences between the test and retest in Tables 2 and 3.

3.1 | Test-retest analyses

Test-retest reliability results and systematic differences of the SDFQ-IT by subscales and total scores are in Table 2. The adequate Cronbach's alpha indicate for the five domains about self-care ($\alpha = .973$), self-management ($\alpha = .964$) and socks and shoes ($\alpha = .981$), as well as for the total SDFQ-IT [$\alpha = .991$]. Excellence test retest reliability (ICC [95%]) for the total SDFQ-IT (ICC = 0.991 [0.984-0.995]), and each sub-domain as shoes and socks (ICC = 0.981 [0.966-0.989]), self-care (ICC = 0.973 [0.952-0.985]) and self-management (ICC = 0.964 [0.936-0.979]) sub-domains. The Spearman's correlations (r_s) between test-retest were adequate for the self-management ($r = .907$), self-care ($r = .954$) and sock and shoes ($r = .958$), and total ($r = .980$).

No differences for dimension and total ($P > .05$).

Figure 1A-D, shows the Bland-Altman plots for the test-retest of each domain and total for study subjects, differences between both measures means within the 95% confidence interval of whole and seems results

4 | DISCUSSION

With regard to recommendation of international guidelines,^{13,18} the SDFQ-IT could use it, as a reliable tool for measuring diabetic foot self-care as the case of aspect related to shoes, habits, hygiene or cutting nails.

TABLE 1 Socio-demographic characteristics of the sample population

	Total group N = 50 Mean \pm SD (IC95%)	Male n = 24 Mean \pm SD (IC95%)	Female n = 26 Mean \pm SD (IC95%)	P value
Age, years	75.78 \pm 10.340 (72.94-78.82)	74.91 \pm 6.54 (72.91-77.368)	76.77 \pm 12.97 (71.53-82.01)	.532
Weight (kg)	76.48 \pm 14.511 (72.36-80.60)	82.45 \pm 2.28 (77.72-87.19)	70.96 \pm 15.20 (64.8277.10)	.004
Height (cm)	1.67 \pm 0.094 (1.64-1.69)	1.74 \pm 0.01 (1.72-1.77)	1.607 \pm 0.61 (1.571-1.62)	<.001
BMI (kg/m ²)	27.32 \pm 4.43 (27.05-28.58)	27.03 \pm 0.75 (25.47-28.59)	24.822 \pm 5.309 (25.52-29.64)	.666

Note: In all the analyses, $P < .05$ (with a 95% confidence interval) was considered statistically significant. *P* values are from Independent *t* student test. Abbreviation: BMI, body mass index.

TABLE 2 Results of test-retest reliability, item-total correlation and systematic differences of the SDFQ-IT according to each domain

Domain	Test (N = 50)			Retest (N = 50)			Correlation test-retest <i>r</i> (<i>P</i>) ^a	Reliability test-retest ICC (95% IC)	Systematic differences test-retest <i>P</i> value ^b
	Mean ± SD (95% CI)	Item-total correlation <i>r</i> (<i>P</i>) ^a	Alpha if item removed	Mean ± SD (95% CI)	Item-total correlation <i>r</i> (<i>P</i>) ^a	Alpha if item removed			
Self-care	19.28 ± 4.15 (18.10-20.46)	.767 (<.01)	.593	18.76 ± 4.49 (17.47-20.04)	.827 (<.01)	.565	.894 (<.01)	0.970 (0.942-0.984)	.009
Self-management	20.06 ± 3.10 (19.18-20.94)	.439 (<.01)	.723	20.14 ± 3.35 (19.19-21.09)	.447 (<.01)	.723	.907 (<.01)	0.964 (0.937-0.980)	0.591
Socks and shoes	16.76 ± 3.72 (15.70-17.82)	.722 (<.01)	.627	16.94 ± 3.59 (15.92-17.96)	.625 (<.01)	.670	.958 (<.01)	0.981 (0.966-0.989)	.260
Total	92.92 ± 12.91 (89.24-96.59)	N/A	.598	92.92 ± 13.01 (89.22-92.62)	N/A	.582	.980 (<.01)	0.991 (0.984-0.995)	.849
Total Cronbach alpha test:			Total Cronbach alpha retest:						
			.812			.804			

Note: *P* value <.05 are considered significative.

Abbreviations: CI 95%; confidence interval 95%; ICC, intraclass correlation coefficient; N/A, not applicable.

^aSpearman test.

^bWilcoxon signed-rank test.

TABLE 3 Results of test-retest reliability, item-total correlation and systematic differences of the SDFQ-IT according to each item

Domain	Item	Test (N = 50)			Retest (N = 50)			Correlation test-retest	Reliability test-retest	Systematic differences test-retest
		Mean ± SD (95% CI)	Corrected item-total correlation	Cronbach's alpha if item deleted	Mean ± SD (95% CI)	Corrected item-total correlation	Cronbach's alpha if item deleted			
Self-care	1. In general, do you check your feet yourself?	2.54 ± 1.03 (2.25-2.83)	.499 (<.001)	.774	2.50 ± 1.01 (2.21-2.79)	.588 (<.001)	.774	.864 (<.001)	0.950 (0.912-0.972)	.527
	2. Do you look for sores and examine the state of the skin of your feet by yourself?	2.52 ± 0.58 (2.36-2.68)	.373 (<.001)	.786	2.4 ± 0.64 (2.24-2.60)	.518 (<.001)	.786	.823 (<.001)	0.898 (0.818-0.942)	.527
	3. Do you inspect your nails?	3.38 ± 0.92 (3.12-3.64)	.727 (<.001)	.756	3.28 ± 0.92 (3.02-3.54)	.781 (<.001)	.756	.922 (<.001)	0.958 (0.924-0.976)	.059
	4. How important do you consider personal care of your feet?	3.28 ± 0.85 (3.04-3.52)	.457 (.001)	.777	3.18 ± 0.91 (2.92-3.44)	.574 (<.001)	.777	.882 (<.001)	0.954 (0.917-0.974)	.059
	5. Regarding the recommendations on how to take care of your feet...	3.90 ± 0.99 (3.62-4.18)	.614 (<.001)	.763	3.76 ± 1.17 (3.43-4.00)	.666 (<.001)	.763	.963 (<.001)	0.951 (0.912-0.973)	.038
	6. To treat skin sores, dry skin patches, and calluses...	3.66 ± 1.18 (3.32-4.00)	.636 (<.001)	.751	3.62 ± 1.24 (3.27-3.97)	.645 (<.001)	.751	.841 (<.001)	0.972 (0.951-0.984)	.480
Self management.	7. To dry your feet...	4.42 ± 0.92 (4.16-4.68)	.641 (<.001)	.759	4.20 ± 1.06 (3.90-4.50)	.772 (<.001)	.759	.851 (<.001)	0.898 (0.807-0.944)	.015
	8. Regarding new shoes. Is it hard to find comfortable shoes for your feet?	4.24 ± 0.84 (3.54-4.48)	.085 (.558)	.804	4.16 ± 0.95 (3.89-4.43)	.114 (.432)	.804	.879 (<.001)	0.921 (0.861-0.955)	.279
	9. How often do you cut or treat your toenails?	3.88 ± 1.20 (3.54-4.22)	.721 (<.001)	.754	3.96 ± 1.17 (3.63-4.29)	.677 (<.001)	.754	.930 (<.001)	0.971 (0.949-0.984)	.157
	10. To dry your feet.	3.54 ± 1.19 (3.20-3.88)	.103 (.477)	.822	3.78 ± 1.14 (3.45-4.11)	-.035 (.811)	.822	.864 (<.001)	0.908 (0.825-0.949)	.004
	11. Regarding socks.	3.98 ± 0.91 (3.72-4.24)	.209 (.145)	.821	4.04 ± 0.90 (3.78-4.30)	-.202 (.150)	.821	.960 (<.001)	0.982 (0.967-0.990)	.083
	12. Regarding conventional footwear, before using it.	3.60 ± 1.16 (3.27-3.93)	.741 (<.001)	.746	3.74 ± 1.08 (3.43-4.05)	.686 (<.001)	.746	.920 (<.001)	0.955 (0.918-0.975)	.038
Shoe and socks	13. Regarding socks	3.20 ± 1.03 (2.91-3.49)	.360 (.010)	.793	3.36 ± 1.10 (3.05-3.67)	.295 (.038)	.793	.902 (<.001)	0.945 (0.898-0.970)	.023
	14. Regarding new shoes. Is it hard to find comfortable shoes for your feet?	3.64 ± 1.10 (3.33-3.95)	.433 (.002)	.782	3.60 ± 1.06 (3.30-3.90)	.061 (.673)	.782	.812 (<.001)	0.927 (0.871-0.959)	.763
	15. Regarding summer footwear, with excessive heat, ...	3.52 ± 0.70 (3.32-3.72)	.255 (.073)	.797	3.32 ± 0.74 (3.11-3.53)	.583 (<.001)	.797	.779 (<.001)	0.898 (0.781-0.948)	.002
	16. To heat your feet...	2.80 ± 1.61 (2.34-3.26)	.671 (<.001)	.779	2.92 ± 1.53 (2.48-3.38)	.499 (<.001)	.779	.953 (<.001)	0.980 (0.963-0.989)	.063

Note: P value <.05 are considered as statistically significant. Abbreviations: 95% CI; 95% confidence interval; ICC, intraclass correlation coefficient; N/A, not applicable. ^aSpearman (r_s) test. ^bWilcoxon signed-rank test.

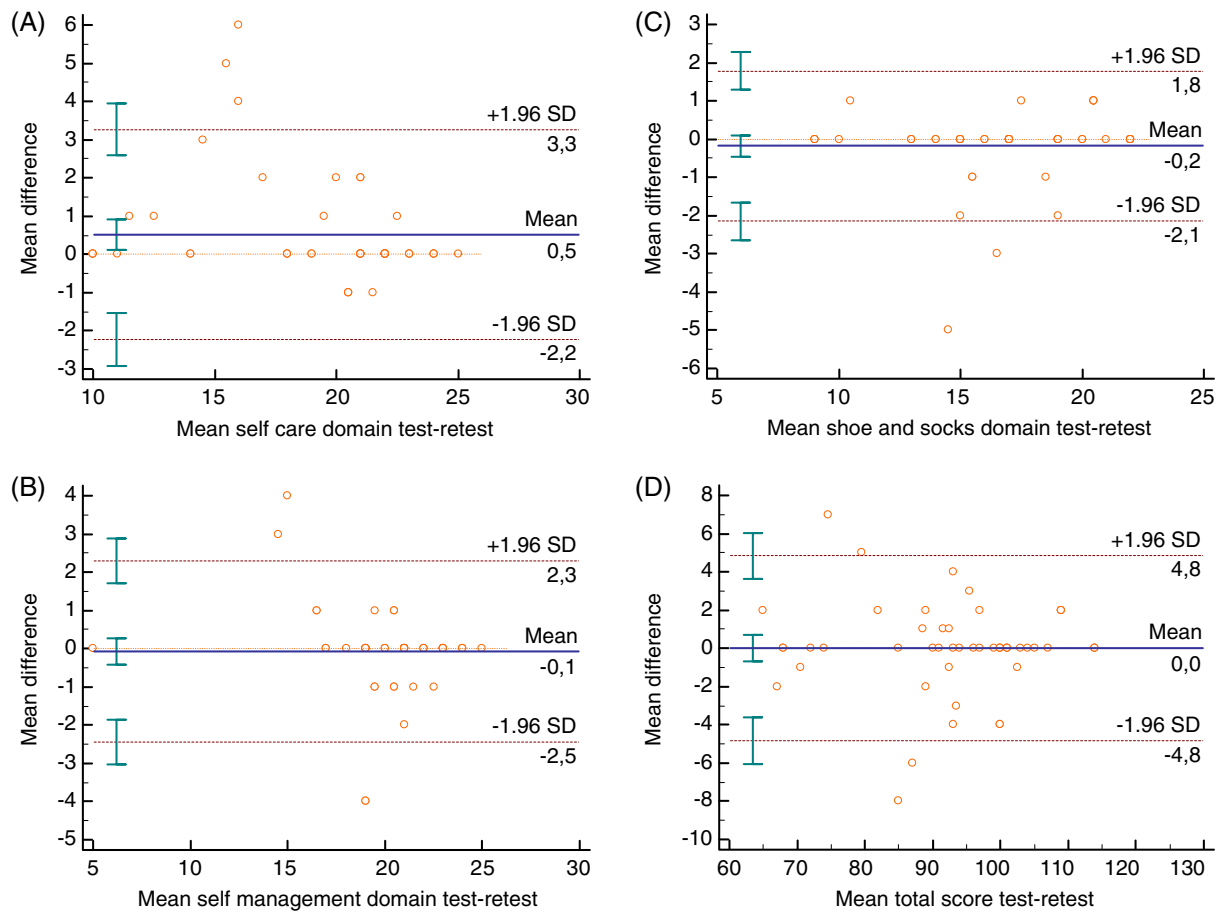


FIGURE 1 Bland-Altman plot showing the agreement between test and retest for the individual subscales and the total score. Dimensions: A, Self-management; B, Self-care; C, Socks and shoes

The SDFQ was developed in Spain with a great degree of reliability and also was translated to French.^{13,14}

Before our study, Italian translated version to validate and adaptate of diabetic foot self-care another clinimetric tool were developed with almost identical effects in case of frailty and foot pain, or even in other foot disorders context.¹³ The achievements of Spanish version of the ROWAN foot pain assessment questionnaire (ROWAN-Sp) or FFI considered as a valid questionnaire in Spanish context for measuring foot disorders with excellent Cronbach's alpha.^{44,45} Moreover, the Spanish [M.F.P.D.I] Manchester questionnaire was a strong clinimetric measure with sub-scales, for example, pain or foot disorders due to an appropriate Rasch model [$\chi^2(2)(df) = 15.945(12), P = .194$], exceptional consistency and unidimensionality were provided.⁴⁶

Lastly, we should consider possible limitations according the research results. Firstly, the SDFQ-IT was developed from podiatry medical clinics university learners perform the exercises, although the initial SDFQ-IT were completed from an podiatric centre.¹³

Secondly, test-retest was completed over and done with a electronical address on this research, while the original SDFQ-IT and other Italian validated scales were developed by head-on the study subject.¹⁻³ As a final point, age arrangement like infant population were not measured on this validate, whereas other tools like the Oxford questionnaire [Ox-A.F.Q] conversion was corroborated from in childhood, 5 to 16 years old.⁴⁷

5 | CONCLUSION

The SDFQ-IT is a useful and trustworthy clinimetric tool with appropriate apply in the Italian community and can be administered in whole or every dimension degree, as, are, self-management; self-care; socks and shoes sub-scales.

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DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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