

Table 1
Sociodemographic features of subjects.

	Total group n 50	Men n 19	Women n 31	P Value
	Mean ± SD Range	Mean ± SD Range	Mean ± SD Range	
	N = 50	N = 19	N = 31	
Age (years)	51.440 ± 17.798 (46.381–56.498)	50.052 ± 18.682 (41.047– 59.057)	52.290 ± 17.493 (45.873–58.706)	0.305
Weight (kg)	76.520 ± 15.654 (72.070–80.969)	82.052 ± 11.578 (76.472–87.633)	73.129 ± 16.987 (66.897–79.360)	0.351
Height (m)	1.65 ± 0.091 (1.630–1.68)	1.734 ± 0.066 (1.707–1.770)	1.605 ± 0.062 (1.582–1.628)	0.010
BMI (kg/m²)	27.918 ± 5.579 (26.332–29.504)	27.094 ± 3.114 (25.593–28.596)	28.423 ± 6.657 (25.981–30.865)	0.098

Abbreviations: BMI, body mass index; SD, standard deviation; Kg, kilograms; M, meters; M², square meter. In all the analyses, P < 0.01 (with a 99 confidence interval) was considered statistically significant. P-values are from Independent student t-test.

measuring foot problems and their impact in the QoL related to foot health. The tool are composing by 6 sub-scales a) walk, b) foot pain, c) hygiene, d) nail care, e) concern, f) health-related QoL, and g) Visual Analogic Scale (VAS). The PHQ was adapted in Spanish with an appropriated concurrent validity [13]. The clinometric tool was administered to podiatric patient populations [14].As regards to the properties and concordance level with other clinimetric tools have been researched previously [15,16]. Furthermore, PHQ register self perception about foot health related QoL.For that reason could be useful for measuring the efficacy of treatments and establish the foot health status marks [16].

As far the PHQ domains, 6 factors can be considered for measuring different QoL dimensions related to foot health disabilities [16]. Therefore, transcultural adaptation methods should be carried out to obtain cross-cultural measurement properties [17,18]. Nowadays, the PHQ has not been adapted or validated in persian [13,14,16,19]. On the other hand, the main advantage of PHQ enables the possibility for measuring foot disabilities self-administrated using sub-scales, as

Table 2
Results of test-retest reliability, Item–total correlation and systematic differences of the PHQ according to each domain.

Domains	Test (N = 50)			Retest (N = 50)			Correlation Test-retest	Reliability Test-retest	Systematic differences Test-retest
	Mean ± SD (95% CI)	Item–total correlation r (P) ^a	Alpha if item removed	Mean ± SD (95% CI)	Item–total correlation r (P) ^a	Alpha if item removed			
Walk	1.54 ± 0.64 (1.35–1.72)	0.846 (<0.01)	0.738	1.60 ± 0.72 (1-39-1-80)	0.832(<0.01)	0.775	0.872 (<0.01)	0.895 (0.815–0.940)	0.317
Hygiene	1.18 ± 0.43 (1.05–1.30)	0.614 (<0.01)	0.765	1.28 ± 0.57 (1.11–1.44)	0.652 (<0.01)	0.789	0.669 (<0.01)	0.675 (0.425–0.815)	0.187
Nail care	1.28 ± 0.57 (1.11–1.44)	0.551 (<0.01)	0.761	1.30 ± 0.61 (1.12–1.47)	0.542 (<0.01)	0.796	0.845 (<0.01)	0.851 (0.737–0.915)	0.785
Foot pain	1.64 ± 0.63 (1.460–1.819)	0.824 (<0.01)	0.746	1.64 ± 0.63 (1.45–1.86)	0.865 (<0.01)	0.779	0.799 (<0.01)	0.860 (0.754–0.921)	0.763
Concern	1.76 ± 0.71 (1.460–1.819)	0.732 (<0.01)	0.752	1.72 ± 0.72 (1.55–1.96)	0.818 (<0.01)	0.788	0.805 (<0.01)	0.893 (0.811–0.939)	0.527
Health-related QoL	1.74 ± 0.63 (1.56–1.91)	0.608 (<0.01)	0.759	1.86 ± 0.60 (1.56–1.91)	0.707 (<0.01)	0.798	0.590 (<0.01)	0.745 (0.851–0.855)	0.145
VAS	2.92 ± 3.08 (2.04–3.79)	0.651 (<0.01)	0.780	2.84 ± 2.81 (2.03–3.64)	0.564 (<0.01)	0.803	0.914 (<0.01)	0.946 (0.905–0.969)	0.847
Total	9.14 ± 2.62 (8.39–9.88)	N/A	0.652	9.42 ± 3.28 (8.48–10.35)	N/A	0.750	0.923 (<0.01)	0.912 (0.845–0.950)	0.350
	Total Cronbach alpha test: 0.772			Total Cronbach alpha retest: 0.808					

Abbreviations: SD, Standard Deviation; CI 95%; confidence interval 95%; ICC, Intraclass Correlation Coefficient; N/A, not applicable, VAS; Visual Analogic Scale; QoL; Quality of Life.

^a Spearman test; ** Wilcoxon signed-rank test. P value < 0.05 are considered significative.

regards to walk hygiene, nail care, worry of the self-perception as well as, a VAS [20], The proposed hypothesis was: carry out the Persian transcultural adaptation of the PHQ.

The main goal of this study was to analyse the psychometric properties of the persian version of PHQ.

2. Material and methods

2.1. Design and sample

A descriptive study, carried out in a podiatry clinic in Iran between November 2022 and January 2023 Employing a translation and test-retest research according to Patient-Reported Outcome Measures (PROMs)- Principles of Good Practice statement and checklist [21,22]. The process for validating and translation were carried out employing the PHQ as a clinimetric tool [23].

2.2. Procedure

Firstly, the translated version of PHQ was developed, secondly the study subjects with foot disabilities were recruited in a podiatry center in Iran. As regards to the sample, all patients voluntarily accepted to participate in the research, moreover they were informed about the procedure and authorized signed their consent. The goal of translation and validation of the PHQ were carried out the properties of it as a clinical instrument [13].

The PHQ was completed by research sample, and they were asked about of ambiguous item and identified it. Moreover, a senior researcher (LA) were asked to review the Persian version of PHQ in terms of content.

2.3. Sample size estimation

The determination of the sample size was developed with G * Power 3.1.9.2 (Heinrich-Heine-Universität Düsseldorf; Düsseldorf, Germany) after testing the correlation between two paired means with respect to the correspondence with a Spearman correlation coefficient of 0.40 and

Table 3
Results of test-retest reliability, Item–total correlation and systematic differences of the PHQ according to each item.

	Test (N = 51)			Retest (N = 51)			Correlation Test-retest	Reliability Test-retest	Systematic differences Test-retest
Items/ Domains	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	r (P)*	ICC (IC95%)	r (P)*
Item 1. Walk	1.54 ± 0.64 (1.35–1.72)	0.846 (<0.01)	0.738	1.60 ± 0.72 (1.39–1.80)	0.832 (<0.01)	0.775	0.872 (<0.01)	0.895 (0.815–0.940)	0.317
Item 2. Foot pain	1.18 ± 0.43 (1.055–1.304)	0.614 (<0.01)	0.765	1.28 ± 0.57 (1.11–1.44)	0.652 (<0.01)	0.789	0.669 (<0.01)	0.675 (0.425–0.815)	0.187
Item 3. Hygiene	1.28 ± 0.57 (1.11–1.44)	0.551 (<0.01)	0.761	1.30 ± 0.61 (1.12–1.47)	0.542 (<0.01)	0.796	0.845 (<0.01)	0.851 (0.737–0.915)	0.785
Item 4. Nail care	1.64 ± 0.63 (1.460–1.819)	0.824 (<0.01)	0.746	1.64 ± 0.63 (1.45–1.86)	0.86 (<0.01)	0.779	0.799 (<0.01)	0.860 (0.754–0.921)	0.763
Item 5. Concern	1.76 ± 0.71 (1.460–1.819)	0.732 (<0.01)	0.752	1.72 ± 0.72 (1.55–1.96)	0.818 (<0.01)	0.788	0.805 (<0.01)	0.893 (0.811–0.939)	0.527
Item 6. Health-related QoL	1.74 ± 0.63 (1.56–1.91)	0.608 (<0.01)	0.759	1.86 ± 0.60 (1.56–1.91)	0.707 (<0.01)	0.798	0.590 (<0.01)	0.745 (0.851–0.855)	0.145
Item 7. VAS	2.92 ± 3.08 (2.04–3.79)	0.651 (<0.01)	0.780	2.84 ± 2.81 (2.03–3.64)	0.564 (<0.01)	0.803	0.914 (<0.01)	0.946 (0.905–0.969)	0.847

Abbreviations: SD, Standard deviation; 95% CI; 95% confidence interval; ICC, Intraclass Correlation Coefficient; N/A, not applicable; VAS; Visual Analogic Scale; QoL; Quality of Life.

* Spearman (r_s) test; ** Wilcoxon signed-rank test. P value < 0.05 are considered as statistically significant.

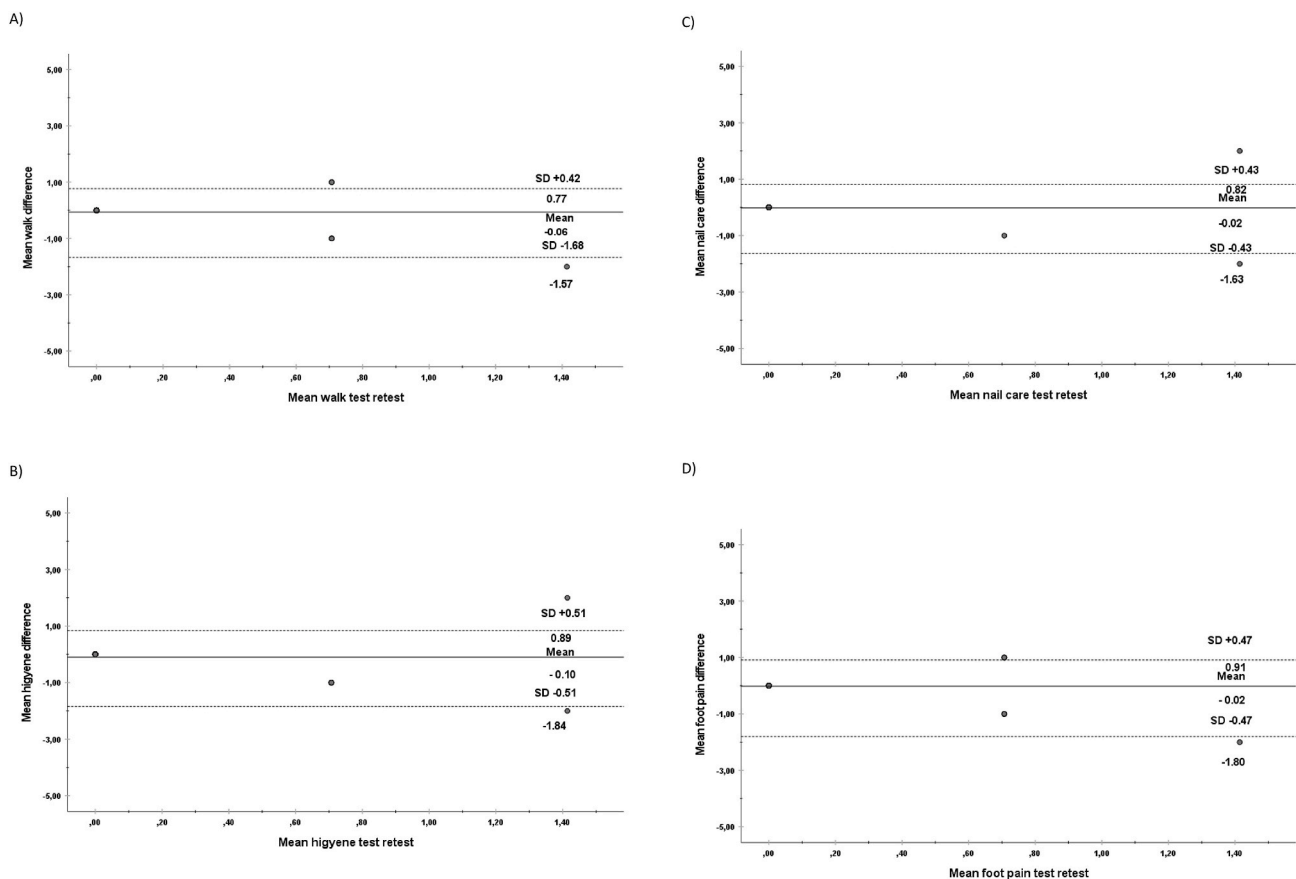


Fig. 1. Bland–Altman plot showing the agreement between test and retest for the individual subscales and the total score. A).

a 95% confidence interval (CI) for a two-tailed test, with an α error of 0.05, an estimated analysis power of 80% (β error = 20%), estimating a final sample size of 46 participants [24].

Fifty patients (31 females and 19 males) were recruited The inclusion criteria was over 18 years old, Persian speakers who were

neighbourhoods on the area around the clinic centre, who present present foot diseases.

Study subjects were excluded if they were not adults, Persian speakers, individuals with an absence of total autonomy in daily tasks, people with cognitive disabilities, people who did not sign their

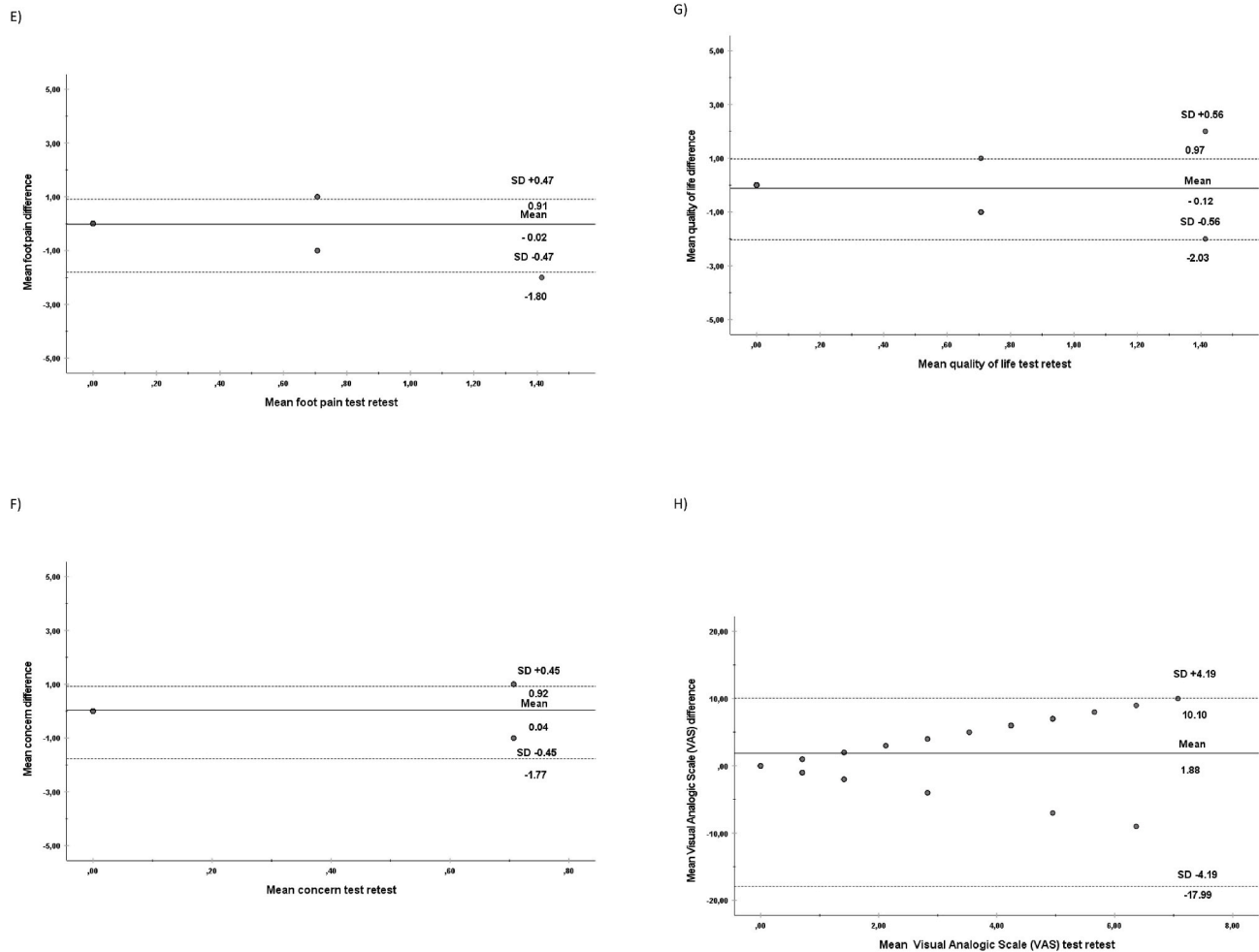


Fig. 1. (continued).

agreement to participate in the study, persons who did not respond to affiliation items or those who did not understand the guidelines to participate.

2.4. Ethical considerations

Ethical approval was obtained from the Committee of the University of Valencia Code.

1243612. In addition, all patients were informed of the study purpose, and their consent was obtained. Ethical standards in human experimentation based on The Declaration of Helsinki were followed [25].

Informed consent was signed from each subject after understanding the purpose and process of the research and the privacy of the subjects' information would have been guaranteed. The fact that their participation was completely voluntary was also highlighted. In addition, the guidelines associated with the ethical standards for research and experimentation on human were preserved as reported in the Declaration of Helsinki, as last modified, the declarations of human rights and biomedicine of the Convention of the Council of Europe.

2.5. Statistic analysis

Whole the variables were tested for normal distribution using the Shapiro Wilks test, and data were considered normal distribution if $P > 0.05$.

Quantitative variables were conveyed as mean \pm SD (IC95%). The

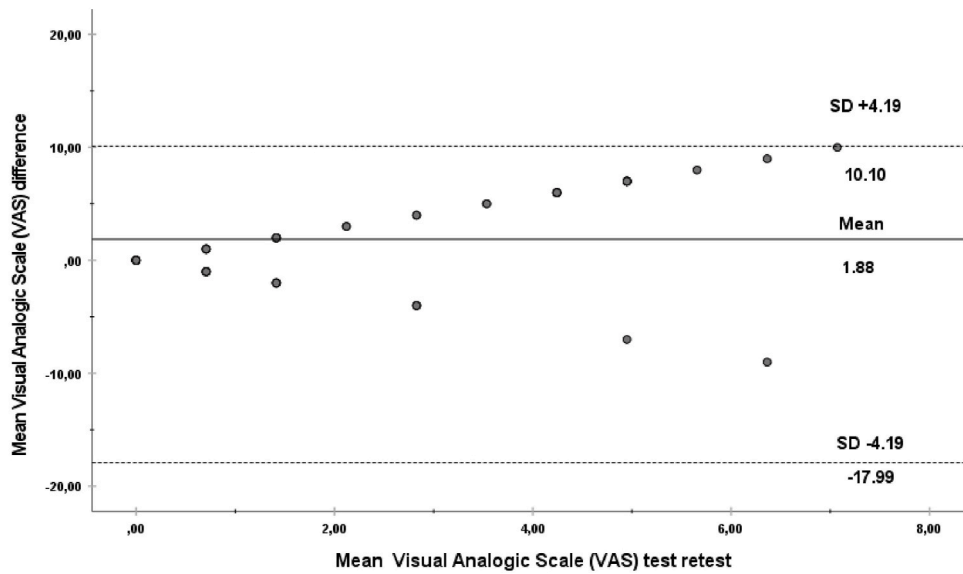
socio-demographic features were recorded.

For parametric records independent t student or U Mann Whitney test for non parametric records were employed to assess differences between groups. Additionally, paired t-test or Wilcoxon signed-rank test will be used for parametric and no parametric data, respectively for the purpose of checking systematic differences between test & re-test., As far to total results and each sub-scale results, internal consistency and reliability were analyzed spending the Cronbach α . This parameter was used to summarize the internal correlations of all items on a scale.

To clarify, above average coefficient (in the bracket between 0.0 and 1.0) was considered more consistent for the measurement as superior likelihood to reflect an essential single variable on the clinimetric tool. We assessed correlations of all items with the complete mark and also whether Cronbach's was enhanced by deletion of any item. We studied correlations of all items with the overall marks employing non-parametric spearman test or parametric pearson test.

Independent Student t-tests were established for if differences were statistically significant when showing a normal distribution. Considering complete marks and each sub-domain, reliability and internal consistency were evaluated beyond intraclass correlation coefficient (ICC) and the Cronbach alpha (α) with a 95% confidence bracket (95% CI), respectively. For the statistical analysis, a two-way random effects model (2.1), individual measures, total agreement, and ICC were calculated to express concordance reliability between the test and post-test. To explain ICC values, we employed benchmarks as proposed by Landis and Koch [26] with <0.20 as slight agreement, 0.21 to 0.40 as reasonable, 0.41 to 0.60 as moderate, 0.61 to 0.80 as considerable, and

I)



J)

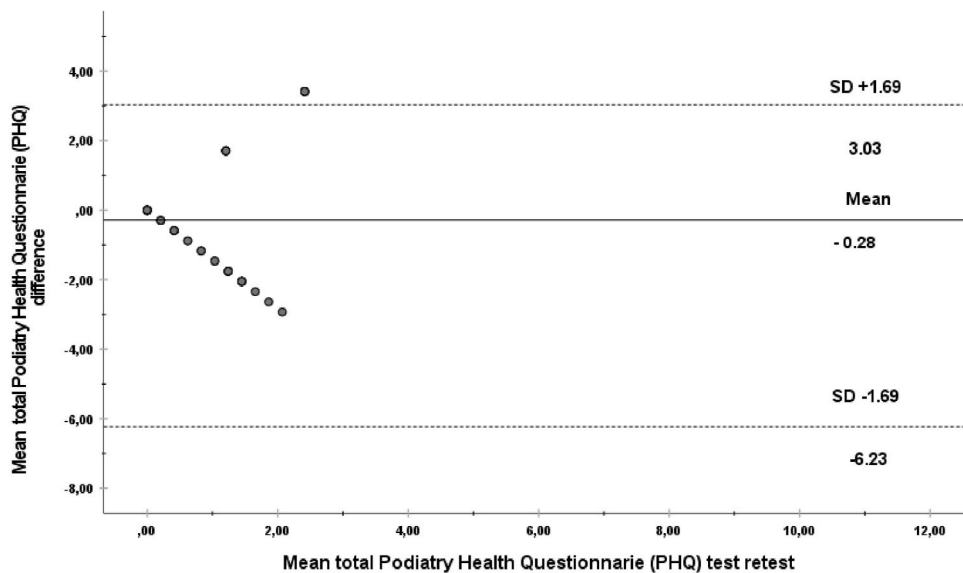


Fig. 1. (continued).

>0.81 as almost perfect. Furthermore, Bland and Altman plots were calculated to evaluate agreement and heteroscedasticity [27].

As far each sub-domain mark and total score, correlation and reliability and internal consistency, were employing through Spearman (r_s), intraclass correlation coefficients [ICC] and the Cronbach's alpha,

respectively. Cronbach's alpha was utilized to define the internal consistency of whole questions on a sub-domain. To clear up, a major coefficient [in the bracket, between 0.0 and 1.0] was contemplated more uniform for the domain with a outstanding possibility to consider a supporting individual variable on the clinimetric instrument.

Correlations of all items were tested with the similarly 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.

A value of $p < 0.05$ with a 95% confidence interval was considered statistically significant for all tests.

All analyzes were calculated with SPSS 25.0v statistical software (IBM Corp., Armonk, NY, USA). Referring to an alpha error of 0.05 for a 95% confidence interval.

2.6. Outcome measurements

All variables studied showed a no normal distribution ($P < 0.05$), except age, weight. Height and Body Mass Index (BMI) showing a normal distribution ($P > 0.05$).

The sociodemographic data are showed in Table 1.

2.7. Test-retest analyses

Results of reliability, pre-test and posttest and systematic differences of the PHQ by items and sub-scales are shown in Tables 2 and 3, respectively. A very good agreement degree was shown for all subscales walk a Cronbach of 0.775 on the subscale nail care 0.789 and 0.796 as regards to hygiene, sub domain foot on pain with 0.779; concern domain with 0.788; quality of life sub scale with 0.798; and visual analogic scale (VAS) 0.803, as for the total score 0.912. An excellent reliability (ICC = 0.912 [95% CI = 0.845–0.950.]) was shown for the total, and each domain such as the items about walk ($\alpha = 0.775$; ICC = 0.895 [95% CI = (0.815–0.940)]), hygiene and nail care ($\alpha = 0.789$; ICC = 0.675 [95% CI = (0.425–0.815)]), and ($\alpha = 0.796$; ICC = 0.851) [95% CI = (0.737–0.915)], foot on pain ($\alpha = 0.779$; ICC = 0.860) [95% CI (0.754–0.921)], concern ($\alpha = 0.788$; ICC = 0.893 [95% CI (0.811–0.939)]), quality of life ($\alpha = 0.798$; ICC = 0.745 [95% CI = (0.851–0.855)]), VAS ($\alpha = 0.803$; ICC = 0.946 [95% CI = (0.905–0.969)]). The test-posttest reliability was excellent for the items about walk (ICC 95%): 0.895 (0.815–0.940), concern 0.893 (0.811–0.939), and VAS, 0.946 (0.905–0.969) There were not differences in any domain ($P > 0.05$) for the mean (SD) difference between pretest and posttest (9.14 ± 2.62 [95% CI = 8.39–9.88]; 9.42 ± 3.28 [95% CI = 8.48–10.35points; $P = 0.350$). Bland and Altman plots visual distributions did not show statistically significant or clinically relevant differences from test to retest (Fig. 1).

The Spearman's correlations (r_s) between test-retest were adequate for the walk ($r = 0.872$), concern ($r = 0.805$) and VAS ($r = 0.914$), and total ($r = 0.923$).

No differences for dimension and total ($P > 0.05$).

Fig. 1 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.

3. Discussion

The outcomes of Spanish version of the Podiatric Health Questionnaire (PHQ) or RADA15 a questionnaire for measuring considered as a valid questionnaire in Spanish context for measuring foot disorders with excellent Cronbach's alpha [17,28]. Besides, the Spanish FAOS questionnaire was a strong clinimetrical measure with sub-scales for example pain or foot disorders with an exceptional consistency and unidimensionality were provided [17].

Furthermore, other prior researches have been carried out on Persian culture, as regards to transcultural adaptation, on diabetic foot, obtained similar results regarding reliability, and with an important clinical message, due to the fact that on that case, a subscale is related to nail care, at the same line of our research achievement.

On the other hand, as far to foot health related quality of life, our

results can be compared to similar research, as the case of chronic foot pain [29], or even on special populations, as the case of hemophiliacs [30], due to the fact that on the case of hemophilia, also is characterized by lower limb disabilities, which usually shows lower health related quality of life as a consequence of musculoskeletal disorders.

Lastly, we should consider possible limitations according the research results. Firstly, the Persian PHQ was developed from podiatry medical clinics university learners perform the exercises, although the initial PHQ were completed from an podiatric center [31]. Secondly, test-retest was completed over and done with a electronical address on this research, while the original PHQ and other Persian validated scales were developed by head-on the study subject [11]. Finally, as regards to the sociodemographic characteristics of the sample, we no found no differences, it could suppose a limitation.

4. Conclusions

The PHQ is a practical and valuable clinical questionnaire with adequate apply in the Persian population and can be used in whole or every dimension degree, as, are, walk, quality of life, hygiene, nail care.

Declaration of competing interest

The authors of this paper certify none conflicts of interest.

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