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Cross-Cultural Adaptation, Validity and Reliability Study of the Italian Version of the Back Pain Functional Scale

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SUMMARY

Introduction. The Back Pain Functional Scale is a scale to assess disability in Low Back Pain patients. The purpose of this study was to translate, culturally adapt and validate the BPFS from the original English language into Italian.

Materials and methods. Translation and cultural adaptation have been performed following international guidelines. 170 italian-speaking subjects with low back pain were recruited; 58 of them also performed the re-test. Internal consistency was assessed by calculating Cronbach's Alpha and test-retest reliability was assessed by calculating the Intraclass Correlation Coefficient (ICC). Exploratory factor analysis and was performed to assess the construct validity and the correlation with other clinical scales was observed through Pearson's correlation coefficients.

Results. High internal consistency (Cronbach's Alpha = 0.912) and very good test-retest reliability (ICC = 0.956) were found. Pearson's correlation coefficient showed statistically significant correlations ($p < 0.01$) with the BPFS, FRI and ODI.

Conclusions. The Italian version of the BPFS showed with good reliability and construct validity. This scale can be considered for the assessment of functional disability in subjects with LBP: short, intuitive and easy to understand. It can certainly be used for both clinical practice and research.

KEY WORDS

Low back pain; evaluation; scale; reliability; validity.

INTRODUCTION

Low back pain is a symptom characterized by a pain located between the lower edge of the costal arch and the lower gluteal folds, sometimes radiating to the lower limbs (1). Low Back Pain (LBP) can be acute, subacute and chronic. LBP is the second most common health problem in the community after the common cold (2), it is considered one of the most frequent diseases: just think that 75-85% of individuals experience it at least once in their lifetime (3).

Physical activity is the main element in the prevention and treatment of low back pain. It does not require expensive materials, therefore providing an accessible intervention in which the patient directly controls pain. Spinal stabilization and the McKenzie approach are two different interventions for the treatment and prevention of low back pain (4).

It is therefore easy to understand how essential it is to investigate this disease and assess it in the most appropriate and correct way possible. In patients with LBP, joint mobility and muscle strength are the most commonly assessed physiological parameters in both clinical practice and research (5). Pain or proprioceptive impairment associated with lumbar spine defects can cause stability deficiencies. Therefore, reduction in the pain and/or improvement of proprioception in these patients could have positive effects on regaining optimal postural balance (6), so it is essential to use objective measurement questionnaires to determine the functional level of a patient with LBP and necessary to implement an effective and successful rehabilitation program (7).

Among the clinical tools to assess disability and functional impairment, patient-reported outcome measures (PROMs) have been reported as effective methods to assess the subjects' perception of the disease due to back pain (8).

Although no gold standard questionnaires to assess disability subjects with LBP has been currently reported (9), the Oswestry disability index (ODI), the Roland and Morris Disability Questionnaire (RMDQ) and the Functional Rating Index (FRI) are commonly used PROMs for this purpose (10-12).

However, they do not present a conceptual framework, data on measurement properties are lacking (13) and finally, these measurements are designed for clinical trials rather than individual clinical practice (14, 15).

To overcome these limitations, Stratford *et al.* formulated The Back Pain Functional Scale (BPFS) for patients with low back pain in 1998. The primary objective was to compensate for the shortcomings of commonly used scales and to create a measure of self-assessment of the patient's functional status that was appropriate for both clinical practice and research (16).

The BPFS is a 12-item assessment scale that measures the patient's ability to perform certain activities in daily life and how low back pain can adversely affect this. The questionnaire takes less than 5 minutes for administration and less than 30 seconds for final scoring (16).

This scale has been translated, validated and culturally adapted in Persian and Turkish (17, 18).

The purpose of this study is to translate and culturally adapt the BPFS for Italian-speaking subjects with LBP, and to assess the validity and reliability of the BPFS.

MATERIALS AND METHODS

The research group of this study is composed of rehabilitation professionals from the Sapienza University of Rome and Department of Rome Aerospace Medicine. After obtaining the written consent of the creators of the Back Pain Functional Scale, the international guidelines of Wild *et al.* and Beaton *et al.* (19, 20) were followed to translate and culturally adapt the original scale into Italian.

Authors certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2008. Informed consent was obtained from all participants for being included in the study. Institutional Review Board approval was not required because the administration of these tool was part of the usual process of assessment of these individuals in clinical practice, the research involved the analysis of data collected such that individual subjects cannot be identified in any way.

Translation and cultural adaptation

As stated above, the international guidelines of Wild *et al.* and Beaton *et al.* have been followed to translate and culturally adapt the BPFS into Italian.

As we can see from **figure 1**, the first translation phase (Forward-Translation) was carried out independently by two physiotherapists: the first Italian with a good knowledge of English; the second native English speaker who has been living in Italy for several years. Both formulated two independent translations. The two translations were then combined by a third independent translator who was not aware of the previous translations, creating a single version optimized in Italian. Subsequently, the optimized single version in Italian was translated into English again by two bilingual translators (Back-Translation). The back-translated version of the scale was compared with the original.

Finally, the final version of the translation was examined by a Focus Group composed of three Physiotherapists, who corrected any spelling, grammar or other errors to minimize the differences between the version obtained and the original English version.

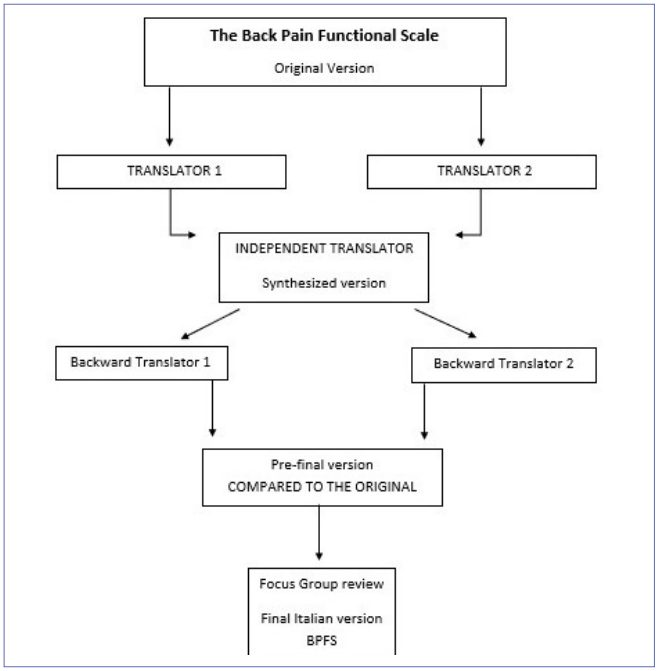

Figure 1. Flowchart of the adaptation of the Back Pain Functional Scale (BPFS) from English into Italian.

Participants

Italian-speaking subjects with LBP, aged 18-65 (17) were included in the study. Patients with rheumatological and neurological diseases, pregnant women, patients with a history of LBP surgery and patients with specific lumbago caused by tumors, fractures or infections were excluded.

Procedures

The administration of the questionnaire took place in the middle of the current health emergency due to the global pandemic by COVID-19. To overcome this problem and to ensure compliance with social distancing legislation, the questionnaires were administered remotely using the Google Forms platform between April and July 2020.

All participants were sent a single link including the informed consent followed by the scales, respectively: BPFS, FRI, ODI and finally VAS/NPRS.

The scales were administered to 183 patients. 13 patients were excluded from the study due to incorrect compilation. 170 patients were finally recruited for this study. 58 out of the included subjects were administered the BPFS twice with one-week time-interval to assess test-retest reliability. The subjects underwent no treatments between the two assessments.

Questionnaires

The Back Pain Functional Scale (BPFS)

The BPFS is a self-administrable scale of 12 items aimed at assessing the patient's ability to perform certain daily life activities including work, domestic, and sports/recreational activities. Each item can be evaluated on a 6-point Likert scale, with a score range from 0 to 5, where 0 indicates the inability to perform the specified activity due to back pain and 5 indicates the absence of difficulties.

The single items scores are simply added together to obtain a final score that can vary from 0, lower functional level, to a maximum of 60 points, higher functional level. This scale requires less than 5 minutes for the administration and less than 30 seconds for the final scoring (21, 22).

Oswestry Disability Index (ODI)

The ODI (21) consists of 10 items, the first item investigates the intensity of pain, and the others assess how much pain can affect daily life activities. Each item has a score from 0 (no pain) to 5 (maximum pain). The final score is obtained by adding the points obtained by each item, dividing this sum by the total possible score (50), and then converting this fraction into a percentage. A higher score reflects a higher disability. The questionnaire is completed in about 5 minutes and the final scoring calculated in less than 1 minute.

The Functional Rating Index (FRI)

The FRI (24) is composed of 10 items also aimed at assessing pain and the ability to perform certain daily activities. Each item is asked to score on a Likert scale ranging from 0 (no pain and ability to perform certain activities) to 4 (worst possible pain and inability to perform certain activities). Then the total score is calculated by adding the scores of the 10 items, dividing this result by the total possible score (40) and then converting this fraction into a percentage. Then you will have 0% - no disability, 100% - severe disability.

The Numerical Pain Rating Scale (NPRS) /VAS

The NPRS (25) is a self-administration tool used to assess the severity of pain. It is a segmented numerical version of the visual analogue scale (VAS) (26) where the patient selects an integer number (0-10) which, as mentioned above, best reflects the intensity of his or her pain. Like the VAS, this is represented by a horizontal line delimited at its extremes, ranging from 0 (no pain) to 10 (worst possible pain). The patient selects a number along this line, at the point that most accurately expresses the perceived pain.

Statistical analysis

All statistical analyses were performed using IBM - SPSS version 25.00 and the level of significance was set for a P-value less than or equal to 0.05.

Following the checklist "Consensus-Based Standards for the Selection of Health Status Measurement Instrument" (COSMIN), the reliability and validity of the culturally adapted scale (27) were evaluated. The reliability of internal consistency was assessed by calculating Cronbach's Alpha, whose values must be in the range 0.7-0-9. This range indicates an excellent homogeneity of the items within the total scale. The test-retest reliability, instead, has been evaluated through the calculation of the Intraclass Correlation Coefficient (ICC). The ICC must assume a value greater than 0.7. Structural validity was also assessed through factorial analysis investigating the validity of the construct. Prior to the factorial analysis, Kaiser Meyer Olkin's (to determine the suitability of the sample) and Bartelett's (to determine the suitability of the sample) tests were used. In order to calculate the construct validity of the BPFS, in addition to our scale, FRI and ODI were also administered, and Pearson Correlation Coefficient were calculated. It was expected to find negative linear correlations for comparison with all three scales, as a higher score in BPFS indicates better health, while a higher score in FRI, ODI and VAS/NPRS indicates worse health.

Table I. Demographic characteristic of the BPFS participants.

	Minimum	Maximum	Mean
Age	18	80	38.91 ± 15.40
Height (cm)	148	190	170.14 ± 9.16
Weight (Kg)	42	103	69.5 ±1 3.28
Gender			
Female	105 (61.8)		
Male	65 (38.2)		

Values are presented as mean ± standard deviation or number (%).

RESULTS

Translation and cultural adaptation

All the items in the final Italian translation of the BPFS were very similar to the items in the original English version. No particular changes were made to the adaptation process, and it was carried out without major difficulties. However, the unit of "mile", which is in item no. 9, was converted to "Kilometer" and, since 1 mile corresponds to 1.5 km, the translation was "walking 1.5 km".

Participants

183 patients with low back pain were suitable for this study; however, 13 patients were excluded from the study due to incorrect compilation. Ultimately, 170 patients, who met the inclusion criteria, were recruited between April and July 2020.

Table I shows the demographic characteristics of the participants.

Reliability

Cronbach's Alpha was 0.912 revealing very good internal consistency. By eliminating one of the items, Cronbach's alpha tends to decrease (**table II**).

Table II. Internal consistency: Cronbach's alpha for the subscales and Cronbach's alpha if item deleted.

	Scale Mean if Item Deleted	Scale Variance if Item Deleted	Corrected Item-Total Correlation	Cronbach's Alpha if Item Deleted
Item1	40.29	70.090	.744	.901
Item 2	40.58	68.316	.755	.900
Item 3	41.01	67.195	.756	.899
Item 4	40.74	68.631	.680	.903
Item 5	40.07	70.362	.598	.907
Item 6	40.67	65.962	.745	.900
Item 7	40.28	74.003	.473	.912
Item 8	40.43	70.045	.616	.906
Item 9	39.99	69.597	.666	.904
Item 10	39.76	70.714	.730	.902
Item 11	40.37	75.170	.416	.914
Item 12	40.12	70.270	.609	.907

The test-retest reliability was very good, with an Intraclass Correlation Coefficient (ICC) of 0.956, which can be seen in **table III**.

Convergent validity

The correlation of the BPFS with FRI was r = -0.835 and ODI was r = -0.828, indicating that the FRI and ODI were strongly correlate with BPFS (**table IV**).

Factorial analysis

As we can see in **table V**, the Kaiser Meyer Olkin and Bartlett test values indicate that the sample was suitable and adequate for factorial analysis. As far as factorial analysis is concerned, the scale had a mono-factorial structure and this can be observed through the Scree plot graph, shown in **figure 2**. According to the total variance analysis, the single factor of BPFS represents 51.733% of the total variance, which supports the questionnaire with a single factor structure.

Table V. Kaiser Meyer Olkin and Bartlett's tests.

KMO and Bartlett's Test		
Kaiser-Meyer-Olkin Measure of Sampling Adequacy		.906
Bartlett's Test of Sphericity	Approx. Chi-Square	1147.503
	df	66
	Sig.	.000

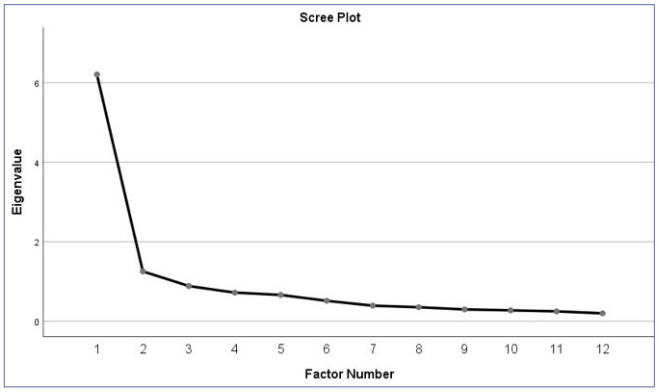

Figure 2. Scree plot graph of the Italian version of the Back Pain Functional Scale.

DISCUSSION

The objective of this study was to carry out a process of translation, cultural adaptation, and validation of the BPFS from the original English language into Italian. The study produced an Italian version of the Back Pain Functional Scale (BPFS) linear and consistent with the original English version. The statistical tests carried out have demonstrated a good reliability and validity of the instrument, resulting in a scale to be taken into real consideration in order to evaluate the Low Back Pain on patients who are affected by it. The selection and the appropriate use of these questionnaires are needed to plan a successful treatment and follow-up (28). The RMDQ and ODI are the commonly used valid and reliable scales, they are not recommended for patients with low back pain for their insufficiency in indicating the level of disability (22), moreover Calamels *et al.* (9) sustain that there is no gold standard for low back pain assessment.

Table III. Stability: intraclass correlation coefficient between test and retest of 58 participants.

Intraclass Correlation Coefficient							
	Intraclass Correlationb	95% Confidence Interval		F Test with True Value 0			
		Lower Bound	Upper Bound	Value	df1	df2	Sig
Average measures	.956[c]	.925	.974	22.187	57	57	.000

Two-way mixed effects model where people effects are random and measures effects are fixed. [a]The estimator is the same, whether the interaction effect is present or not. [b]Type A intraclass correlation coefficients using an absolute agreement definition. [c]This estimate is computed assuming the interaction effect is absent because it is not estimable otherwise.

Table IV. Validity: Pearson correlation coefficient between BPFS, FRI and ODI.

Correlations				
		Total BPFS	Total ODI	Total FRI
Total BPFS	Pearson Correlation	1	-.828**	-.835**
Total ODI	Pearson Correlation	-.828**	1	.840**
Total FRI	Pearson Correlation	-.835**	.840**	1

**Correlation is significant at the 0.01 level (2-tailed).

The RMDQ is recommended to be used in combination with other measures when low back pain is associated with psychological or social problems. Compared with RMDQ, the BPFS has better internal consistency, test–retest reliability, and point estimate of susceptibility to change, suggesting its superiority over RMDQ (18, 22, 29). However, we did not use RMDQ for the assessment of convergent validity assuming a better correlation between BPFS and FRI.
In the Turkish version of the questionnaire Maras *et al.* (18) recruited only patients with chronic low back pain in order to obtain a homogeneous group. Stratford *et al.* (16) who created the original version of the BPFS, and Nakhostin Ansari *et al.* (17) too, who conducted the Persian version, did not separately report the status of patients for acute, subacute, or chronic low back pain, as well as in our study with the aim of being able to use the scale on a larger pool of patients.
Internal consistency was assessed by calculating Cronbach's Alpha, which is 0.912; this value is statistically significant as it is higher than 0.7. The value is highly comparable to the Persian version ($\alpha = 0.90$) and the Turkish version ($\alpha = 0.910$). The Italian version of the BPFS has a very good level of internal consistency. We note from **table II** that all items are indeed relevant to the scale. In fact, if one of them were to be eliminated, Cronbach's Alpha value would tend to decrease, thus reducing the internal consistency of the scale.
The test-retest reliability was assessed by calculating the Intraclass Correlation Coefficient (ICC) which assumes a value of 0.956 (0.925-0.974). This value is highly comparable with the Turkish version data (ICC = 0.958) and higher than the Persian version data (ICC = 0.88). Considering the ICC values, it is possible to say that the Italian version of the BPFS has an excellent stability and this indicates that after repeated measurements, the instrument offers comparable results (**table III**). It has therefore been demonstrated that, following repeated administration to the same patient after one week and in the absence of treatment, the instrument remains stable.
The validity of the construct was assessed by comparing the BPFS scores with the FRI and ODI scores, calculating the Pearson Correlation Coefficient. All correlations were statistically significant with a $p < 0.01$. From this we can deduce that the Back Pain Functional Scale correlates well, through a negative linear correlation, with the Functional Rating Index and with the Oswestry Disability Index.
Tests by Kaiser Meyer Olkin and Bartlett showed that the sample was suitable and adequate for factorial analysis, which revealed that the BPFS had a single factor structure.
The study was therefore conducted on a pool of patients with both acute and chronic low back pain and this could represent a limitation due to the heterogeneity of the sample, so in future the scale could be selectively evaluated on patients with acute pain, subacute pain and chronic pain, as well as in Turkey where actually the scale has been validated only on chronic patients. On the other hand, however, the evaluation tool obtained in our country lends itself – having proved valid – to a wider use.

CONCLUSIONS

This study consists of translation, cultural adaptation and validation of the Back Pain Functional Scale (BPFS).
From the analysis of the collected data, statistically significant results have all emerged and it has been demonstrated that the Italian version of the BPFS has good psychometric properties. It has an excellent internal consistency, test-retest analysis, and construct validity, so it has been proven that we are dealing with a valid and reliable instrument.
The scale is short, intuitive, and easy to understand, both for health professionals and for the patient who has to fill it in. It will therefore be of fundamental importance to set up a good rehabilitation program, allowing us to evaluate the progress made following the rehabilitation of patients suffering from Low Back Pain.
The Back Pain Functional Scale is an excellent evaluation tool for LBP, which can be used alongside the main gold standards and can certainly be used as diagnostic and evaluation support in both medical and physiotherapeutic fields.

FUNDINGS

None.

DATA AVAILABILITY

Data are available to the following repository link: https://docs.google.com/spreadsheets/d/1-JOIEacsV6_7TOpgcsOUF1RNJ2i2icmY/edit?usp=sharing&ouid=100833025615805537002&rtpof=true&sd=true.

CONTRIBUTIONS

All authors contributed equally to this work.

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CONFLICT OF INTERESTS

The authors declare that they have no conflict of interests.

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