



# Turkish version of Parkinson Fatigue Scale: Validity and reliability study of binary scoring method

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## ABSTRACT

**Objectives:** The aim of the present study was to translate and cross-culturally adapt the Parkinson Fatigue Scale (PFS) into Turkish and to evaluate its reliability and validity.

**Patients and methods:** Between September 2015 and May 2016, a total of 138 patients (84 males, 54 females; mean age 62.8±9.3 years; range, 42 to 83 years) with Parkinson's disease (PD) were included in this study. The Turkish version of the PFS was analyzed for data quality, scaling assumptions, acceptability, reliability, and validity. We used the binary scoring method of the Parkinson Fatigue Scale.

**Results:** The data quality for the Turkish version of the PFS was excellent. The scaling assumption was acceptable. The scale provided an acceptable internal consistency (Cronbach's alpha was 0.955 for a test and 0.941 for a retest, and corrected item-to-total correlations were ranged from 0.478 to 0.849. The test-retest reliability (correlation coefficients were ranged from 0.650 to 0.875) was adequate. Although the total binary score of the PFS was not associated with demographic and clinical data, it was significantly correlated with some of the clinical rating scale scores, including the Unified Parkinson's Disease Rating Scale, Schwab & England Activities of Daily Living Scale, Hospital Anxiety and Depression Scale, Epworth Sleepiness Scale, Pittsburg Sleep Quality Index, 36-item Short Form Health Survey, 39-item Parkinson's Disease Questionnaire, and Fatigue Severity Scale.

**Conclusion:** The Turkish version of the PFS is an acceptable, valid, and reliable tool for the assessment of fatigue in PD patients.

**Keywords:** Adaptation; binary scoring method; Parkinson Fatigue Scale; reliability; validity.

Parkinson's disease (PD) is a common, chronic, progressive, and disabling neurological condition which affects 1 to 2 per 1,000 of the general population.<sup>[1]</sup> Its incidence and prevalence increase with age. It is the second most common neurodegenerative disorder after Alzheimer's disease.<sup>[1]</sup> Parkinson's disease is typically characterized by motor dysfunction such as resting tremor, rigidity, bradykinesia, postural instability and gait disturbance, and also by non-motor symptoms such as sleep disorders, pain, depression, fatigue, and cognitive impairments. Although motor symptoms are the cardinal features of PD, non-motor symptoms are many times more troublesome and debilitating than motor symptoms.<sup>[2]</sup> Fatigue is one of the most common annoying and disabling non-motor symptom in PD

and may have a negative impact on the quality of life of patients with PD.<sup>[3,4]</sup> It affects more than half of the PD patients.<sup>[5]</sup>

The disability in PD is multidimensional, complex, and fluctuating. Thus, the role of clinicians in the management of PD is multidimensional. The goal of intervention is to help minimize the patient's disability and maximize the ability to live independently. Problems faced by rehabilitation specialists during intervention essentially stem from non-motor symptoms. These symptoms have been increasingly understood as a significant contributor of disability in PD. In recent years, the instruments evaluating specific non-motor symptoms gained much popularity. Reliable and valid instruments that are easy to administer and

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comprehensively reflect the patient's disease status are invaluable to both clinical practice and research.<sup>[6]</sup> It is also equally important to validate these instruments by testing the translational/cross-cultural adaptation.

Various generic and disease-specific fatigue rating scales are used to evaluate fatigue in patients with PD.<sup>[7]</sup> The Parkinson Fatigue Scale (PFS) is a disease-specific, 16-item patient-rated scale that was used to evaluate single construct reflecting the physical aspects of fatigue and to assess both the presence of fatigue and its impact on daily function in patients with PD. Each item response ranges from 1 (strongly disagree) to 5 (strongly agree).<sup>[7,8]</sup> The scale has three different scoring options; (i) a total PFS score, the average item score across all items, ranges from 1 to 5; (ii) a binary scoring method yields scores from 0 to 16, with positive scores for each item generated by agree and strongly agree responses; and (iii) calculates a total PFS score, range 16 to 80, based on the sum scores for the all individual items.<sup>[7,8]</sup> In the present study, we aimed to translate and cross-culturally adapt the PFS into Turkish and to evaluate its reliability and validity.

## PATIENTS AND METHODS

This was a methodological, validity, and reliability study. A face-to-face interview was performed.

Between September 2015 and May 2016, a total of 171 patients who were admitted to the Movement Disorders Clinic were screened. After 33 patients were excluded (13 patients with an MMSE score <24, 7 patients with secondary Parkinsonism and other neurodegenerative or neurological disorders, 13 patients with insufficient cooperation or incomplete data), a total of 138 patients (84 males, 54 females; mean age 62.8±9.3 years; range, 42 to 83 years) were evaluated for this study. Diagnosis was confirmed according to the UK Parkinson's Disease Society Brain Bank criteria.<sup>[9]</sup> The eligibility criteria included age ≥40 years, Mini-Mental State Examination (MMSE) score ≥24, and literate in Turkish. Exclusion criteria were as follows: (i) individuals presenting with secondary or atypical Parkinsonism, (ii) a previous history of deep brain stimulation surgery, dementia, and other neurodegenerative or neurological disorders, and (iii) use of antidepressants, hypnotics, sedatives, or antipsychotics. All assessments were performed, while the patients received optimized dopaminergic medication and were "on" periods.

The demographic and clinical characteristics were recorded at the initial visit.

## Assessment tools

The following outcome measures were used to assess PD patients:

- *Clinician-based instruments:* Hoehn & Yahr (H&Y) stage, Unified Parkinson's Disease Rating Scale (UPDRS), and Schwab & England (S&E) Activities of Daily Living (ADL) Scale;
- *Patient-based instruments:* Hospital Anxiety and Depression Scale (HADS), MOS 36-item Short-Form Health Survey (SF-36), 39-item Parkinson's Disease Questionnaire (PDQ-39), Epworth Sleepiness Scale (ESS), Pittsburg Sleep Quality Index (PSQI), and Fatigue Severity Scale (FSS).

The H&Y staging is a widely accepted system for overall functional disability. The original scale defined five stages of progressive impairment and disability: Stage 1, unilateral involvement only, usually with minimal or no functional disability; Stage 2, bilateral or midline involvement without impairment of balance; Stage 3, bilateral disease, mild to moderate disability with impaired postural reflexes, physically independent; Stage 4 severely disabling disease, still able to walk or stand unassisted; and Stage 5, confinement to bed or wheelchair unless aided.<sup>[10]</sup> The UPDRS is used to assess impairment and disability. The scale consists of four parts: Part I, mentation, behavior and mood (4 items, 0-16 points); Part II, activities of daily living (13 items, 0-52 points); Part III, motor examination (14 items with 26 total scores, 0-104 points); and Part IV, complications (11 items, 0-23 points). The higher UPDRS subscores indicate more problems.<sup>[11]</sup> The S&E ADL scale is a tool of measuring a person's ability to perform daily activities in terms of speed and independence through a percentage figure. One hundred percent indicates a completely independent individual and 0% indicates an individual in who is no longer functioning.<sup>[12]</sup>

The HADS is used to evaluate the severity of symptoms of anxiety and depression. The scale is a 14-item questionnaire comprising two subscales: the HADS-A (7 items, 0-21 points) assessing the symptoms of anxiety and the HADS-D (7 items, 0-21 points) assessing the symptoms of depression. Higher scores indicate greater anxiety and depression.<sup>[13,14]</sup> The SF-36 has been used to assess the health status of patients. The scale consists of 36 questions in eight domains. A score between 0 and 100 is calculated for each domain, and for the summary scales for physical and mental function, which are weighted averages of the individual

domain scales. Higher scores reflect better health status.<sup>[15,16]</sup> The PDQ-39 is used to measure the quality of life. The scale is composed of 39 items grouped in eight subscales. Subscale scores range from 0 to 100. A PDQ-39 Summary Index is the arithmetic mean of the subscales. Higher scores represent a worse quality of life.<sup>[17]</sup> The ESS is used to assess daytime sleepiness presence and severity. The scale consists of eight items. A total score ranged from 0 to 24, the scores >10 indicate increased daytime sleepiness.<sup>[18]</sup> The PSQI is used to evaluate sleep quality and examine sleep habits and disturbances. The scale consists of 19 questions that are combined to form seven component scores. A total score ranged from 0 to 21. A higher score indicates more several difficulties in the specific areas.<sup>[18]</sup>

The FSS is a uni-dimensional generic fatigue rating scale. The scale consists of nine items and emphasizes the functional impact of fatigue. The total score represents the mean scores of the nine items, ranged from 0 to 7. The higher scores represent a higher level of fatigue.<sup>[7,19]</sup>

### Translation and cross-cultural adaptation

The original version of the PFS was obtained with the permission of Dr. Brown. The translation and cross-cultural adaptation of the PFS to Turkish followed the rules of a previously published guideline;<sup>[20]</sup>

- Translation from English to Turkish by four bilingual translators independently (three physical medicine and rehabilitation specialist and one neurologist),
- Synthesis of four translated versions of PFS and creation of a single consensus text,
- Back translation of a single consensus text by two persons with the source language (English) as their mother tongue,
- Expert committee review, and produce the pre-final version,
- Pretesting of the pre-final version in 20 PD patients to assess the appropriateness and the comprehensibility. Finally, the final version of the PFS was refined and corrected based on feedback from the patients.

### Ethical aspects

The Local Ethical Committee approved this study (27/02/2012, 01/36), and the patients were informed about the content of the study and their informed consent was obtained. The study was conducted in accordance with the principles of the Declaration of Helsinki.

### Statistical analysis

Statistical analysis was performed using the MedCalc for Windows, version 15.0 (MedCalc Software, Ostend, Belgium), the MPlus for Windows, demo version 7.1 (Muthen&Muthen, 2012). The demographic data and clinical characteristics of the patients were presented in mean  $\pm$  standard deviation (SD) or number and frequency (%). The instrument scores were expressed in in mean  $\pm$  SD.

The psychometric properties of the Turkish version of the PFS were obtained using standard methods<sup>[21]</sup> and based on previous studies.<sup>[22,23]</sup> The missing data (%) and computable scores (%) were identified for data quality. Missing data rates <5% were considered adequate and acceptable.<sup>[24]</sup> The mean item scores (SD), corrected item-to-total correlations were identified for scaling assumptions. corrected item-to-total correlations  $\geq 0.30$  were considered adequate.<sup>[25]</sup> Score range, mean and median scores, floor and ceiling effects, and skewness were identified for acceptability. The floor or ceiling effects <15% were considered acceptable.<sup>[26]</sup> The limits for skewness were -1 to +1.<sup>[27]</sup> The reliability was assessed using the internal consistency and test-retest reliability. The retest was performed at 10 to 14 days following the initial assessment. The Cronbach's alpha and corrected item-to-total correlations were calculated for internal consistency. The Cronbach's alpha  $\geq 0.70$ <sup>[21]</sup> and corrected item-to-total correlations  $\geq 0.30$ <sup>[25]</sup> were considered acceptable. The intraclass correlation coefficients and Spearman's rho correlation coefficient were calculated for test-retest reliability and were classified as 0.70-1.0 was considered high, 0.30 to 0.69 moderate, and less than 0.30 low.<sup>[28]</sup> The validity was evaluated by construct (factorial and convergent) validity. Exploratory factor analysis was conducted to examine whether a single factor could be identified, a one-factorial confirmatory factor analysis (CFA) for categorical data was used to test whether each set of items measured a single unidimensional construct. Items with factor loadings below 0.40 were eliminated.<sup>[29]</sup> The Tucker Lewis Index (TLI:>0.90 acceptable, >0.95 excellent), the Comparative Fit Index (CFI:>0.90 acceptable, >0.95 excellent) and the Root Mean Square Error of Approximation (RMSEA:<0.08 acceptable, <0.05 excellent) were used as goodness-of-fit statistics.<sup>[30]</sup> The Spearman's rho correlation coefficients were calculated to assess the correlations between a binary score of PFS with the demographic and disease characteristics, and rating scale scores. Correlation coefficients were classified as 0.70 to 1.0 high, 0.30 to 0.69 moderate, and less

**Table 1.** Sociodemographic and disease characteristics of the patients

Variable	n	%	Mean±SD	Range
Age (year)			62.8±9.3	42-83
Sex				
Male	84	60.9		
Employment status				
Employed	6	4.3		
Unemployed	87	63.1		
Housewife	45	32.6		
Marital status				
Single	6	4.3		
Married	112	81.2		
Divorced	2	1.4		
Widow	18	13.0		
Education time (year)			9.2±2.5	5-14
Education status				
Primary	14	10.1		
Secondary	75	54.3		
High school	31	22.5		
University	18	13.0		
Comorbidities				
Cardiac	56	40.6		
Respiratory	8	5.8		
Diabetes mellitus	31	22.5		
Thyroid	8	5.8		
Rheumatologic	6	4.3		
Psychiatric	19	13.8		
Mini-Mental Status Examination Score			27.3±2.0	24-30
Hoehn and Yahr stage			2.2±1.0	1-4
Hoehn and Yahr stage				
1	42	30.4		
2	39	28.3		
3	41	29.7		
4	16	11.6		
Disease duration (year)			5.1±3.0	1-17
Disease duration				
≤5 years	85	61.6		
>5 years	53	38.4		
Levodopa dose (mg/day)			401.1±268.0	0-1400.0
Levodopa equivalent dose			715.9±339.7	100-1972.5
Unified Parkinson's Disease Rating Scale score				
I			2.6±2.0	0-11
II			11.4±7.2	2-31
III			31.9±17.1	2-71
IV			2.3±2.7	0-12
Total			48.2±26.2	11-115
Schwab and England Activities of Daily Living scale score			82.2±11.5	50-100
Hospital Anxiety and Depression Scale				
Anxiety subscale			8.0±4.0	1-20
Depression subscale			8.4±4.4	0-20
Epworth Sleepiness Scale			7.5±4.5	1-21
Daytime sleepiness	32	23.2		
Pittsburg Sleep Quality Index score				
Total			9.9±4.7	2-20
Short Form-36 score				
Physical Component score			34.2±10.2	17.8-58.3
Mental Component score			42.7±8.3	21.6-59.9
Parkinson's Disease Questionnaire-39 score				
Summary Index			36.9±16.4	2.86-82.34
Fatigue Severity Scale score			4.74±1.67	1.22-6.78

SD: Standard deviation.

**Table 2.** Descriptive statistics of the Turkish version of the Parkinson Fatigue Scale

Item	Test			Corrected item-to-total correlation	Alpha if item deleted	Retest			Test-retest	
	Mean±SD	Median	Min-Max			Mean±SD	Median	Min-Max	Intraclass correlation coefficient (95% CI)	
1	0.38±0.49			0.648	0.953	0.45±0.50			0.650	0.542 to 0.737
2	0.46±0.50			0.618	0.953	0.48±0.50			0.783	0.708 to 0.840
3	0.62±0.49			0.634	0.953	0.56±0.50			0.693	0.595 to 0.770
4	0.54±0.50			0.766	0.950	0.53±0.50			0.680	0.579 to 0.760
5	0.46±0.50			0.754	0.951	0.47±0.50			0.855	0.802 to 0.894
6	0.52±0.50			0.718	0.951	0.51±0.50			0.753	0.671 to 0.817
7	0.62±0.49			0.802	0.950	0.64±0.48			0.845	0.789 to 0.887
8	0.59±0.49			0.848	0.949	0.57±0.50			0.777	0.702 to 0.836
9	0.65±0.48			0.669	0.952	0.67±0.47			0.660	0.555 to 0.745
10	0.66±0.48			0.676	0.952	0.70±0.46			0.770	0.693 to 0.830
11	0.57±0.50			0.832	0.949	0.59±0.49			0.807	0.740 to 0.858
12	0.38±0.49			0.563	0.954	0.32±0.49			0.847	0.792 to 0.888
13	0.57±0.50			0.832	0.949	0.56±0.50			0.853	0.800 to 0.893
14	0.46±0.50			0.770	0.950	0.47±0.50			0.840	0.783 to 0.883
15	0.61±0.49			0.833	0.949	0.61±0.49			0.757	0.675 to 0.820
16	0.60±0.49			0.759	0.950	0.57±0.50			0.749	0.665 to 0.814
Total	8.70±6.05	10.5	0-16			8.70±5.78	10.0	0-16	0.872	0.825 to 0.907*

SD: Standard deviation; CI: Confidence interval; \* Spearman's correlation coefficients.

than 0.30 low.<sup>[28]</sup> A *p* value of <0.05 was considered statistically significant.

### RESULTS

The mean disease duration, the mean levodopa dose, and the mean levodopa equivalent dose were 5.1±3.0 years, 401.1±268.0 mg/day, and 715.9±339.7 mg/day, respectively. The mean H&Y stage and the

mean UPDRS score were 2.2±1.0 and 48.2±26.2, respectively. Other demographic and clinical data of patients are presented in Table 1.

The percentage of missing data was 0% for items, and the percentage of computable scores was 100%. Descriptive statistics of the Turkish version of the PFS are shown in Table 2. The means scores of items were between 0.38±0.49 and 0.66±0.48 at baseline,

**Table 3.** Correlations coefficients of the total binary score of Parkinson Fatigue Scale with various variables

Variables	Correlation coefficients	95% CI	<i>p</i>
Age	0.071	-0.098 to 0.235	0.410
Education time	0.149	-0.019 to 0.308	0.082
Mini-mental Status Examination	-0.145	-0.304 to 0.023	0.091
Hoehn and Yahr stage	0.183	0.017 to 0.339	0.032
Disease duration	0.145	-0.023 to 0.304	0.090
Levodopa dose	0.136	-0.031 to 0.297	0.111
Levodopa equivalent dose	0.126	-0.042 to 0.287	0.141
Unified Parkinson's Disease Rating Scale			
I	0.179	0.013 to 0.336	0.035
II	0.203	0.037 to 0.358	0.017
III	0.171	0.004 to 0.329	0.045
IV	0.085	-0.083 to 0.249	0.320
Total	0.204	0.038 to 0.359	0.016
Schwab and England Activities of Daily Living	-0.202	-0.357 to -0.036	0.017
Hospital Anxiety and Depression Scale			
Anxiety subscale	0.174	0.007 to 0.332	0.041
Depression subscale	0.272	0.110 to 0.420	0.001
Epworth Sleepiness Scale	0.240	0.076 to 0.391	0.005
Pittsburg Sleep Quality Index	0.193	0.027 to 0.349	0.023
Short Form-36 Health Survey			
Physical Component score	-0.504	-0.619 to -0.368	<0.001
Mental component score	-0.360	-0.497 to -0.205	<0.001
39-item Parkinson's Disease Questionnaire Summary Index	0.472	0.331 to 0.593	<0.001
Fatigue Severity Scale	0.648	0.540 to 0.736	<0.001

CI: Confidence interval.

and between  $0.32\pm 0.49$  and  $0.70\pm 0.46$  during retest. The corrected item-to-total correlations were between 0.563 and 0.848. The mean total binary score of PFS score was  $8.70\pm 6.05$  at baseline and was  $8.70\pm 5.78$  during retest. The floor effect was 15.2% and 15.9%, and the ceiling effect was 14.5% and 13.0% for test and retest, respectively. Skewness was -0.271 in test and -0.335 in the retest.

The Cronbach's alpha was 0.954 for the first test and 0.941 for the retest. Deleted items did not lead to an increase in alpha. The test-retest reliability (ICC) for items ranged from 0.650 to 0.855, and Spearman's rho correlation coefficient (SCC) was 0.872 for the overall score of PFS.

An exploratory factor analysis of the items revealed a single factor explaining 59.7% of variance with factor loadings in the range 0.61 to 0.87. The goodness-of-fit statistics for the one-factorial CFA were  $TLI=0.993$ ,  $CFI=0.994$  and  $RMSEA=0.062$  for a single factor. When the demographic, disease and clinical characteristics, and scores of rating scales were compared with the overall score of the PFS, there was no statistically significant difference between the PFS scores and demographic data, such as age, education time, and MMSE, and disease characteristics, such as disease duration, levodopa dose, and levodopa equivalent dose. However, it was significantly correlated with clinical rating scales, including H&Y (SCC, 0.183,  $p=0.032$ ), UPDRS part I (0.179,  $p=0.035$ ), UPDRS part II (SCC 0.203,  $p=0.017$ ), UPDRS part III (SCC 0.171,  $p=0.045$ ), UPDRS total score (SCC 0.204,  $p=0.016$ ), S&E ADL scale score (SCC -0.202,  $p=0.017$ ), HADS Anxiety and Depression subscale score (SCC 0.174,  $p=0.041$  and SCC 0.272,  $p=0.001$ , respectively), ESS score (SCC 0.240,  $p=0.005$ ), PSQI score (SCC 0.193,  $p=0.023$ ), SF-36 PCS (SCC -0.504,  $p<0.001$ ) and MCS score (SCC -0.360,  $p<0.001$ ), PDQ-39 SI score (SCC 0.472,  $p<0.001$ ), and FSS total score (SCC 0.648,  $p<0.001$ ).

## DISCUSSION

The current study shows that the Turkish version of the PFS is a valid and reliable instrument to assess fatigue in PD patients.

The psychometric properties of PFS have been evaluated in five previous studies. To investigate the psychometric properties of the PFS, the original scoring method and the binary scoring method of the scale in the original British English<sup>[8]</sup> and Chinese versions,<sup>[31]</sup> and the original scoring method of the

scale in the American English,<sup>[32]</sup> Brazilian<sup>[33]</sup> and Swedish<sup>[34]</sup> versions were used. In the present study, we used the binary scoring method of the PFS.

The data quality for the present study was excellent, no missing data was detected. With few exceptions, scaling assumptions and acceptability of the scale were often adequate and acceptable. The floor effect of the mean score of the PFS remained slightly higher (15.2% in test and 15.9% in retest) with a acceptable limit of 15% and, the ceiling effect was within acceptable limits. Compared to the Chinese version (floor and ceiling effects were 17.39% and 4.31%, respectively),<sup>[31]</sup> the results from both versions were similar. When the original scoring system was used, no floor and ceiling effects were found in the Brazilian<sup>[33]</sup> and Swedish<sup>[34]</sup> versions. Also, in the Chinese version, the floor and ceiling effect was low (5.21 and 0.90).<sup>[31]</sup> This difference is possibly due to the dichotomous format of their response choices.

The internal consistency of the Turkish version of the PFS was considered satisfactory. Also, the Cronbach's alpha and corrected item-to-total correlations using the binary scoring method were quite similar to the Chinese version (0.94 and 0.55-0.82, respectively). In the present study, the test-retest interval was 10 to 14 days. The ICC value for the overall score was between the original English version (0.83)<sup>[8]</sup> and the Chinese version (0.94).<sup>[31]</sup> This difference was probably due to the test-retest intervals. While the time interval was approximately two weeks in the first study, it was seven days in the other. A lower time interval was usually associated with improved retest analysis results.<sup>[35]</sup>

In present study, we showed that there was a relationship between the severity of fatigue and the disability due to PD (UPDRS and S&E ADL scale), the symptoms of anxiety and depression (HADS), sleep disorders (ESS and PSQI), health status (SF-36), and quality of life (PDQ-39). Consistent with our study, similar results were found in the other language versions used to the original scoring method of the scale.<sup>[31,33,34]</sup> It is known that there is a close relationship between anxiety, depression, sleep disorders, quality of life, and fatigue.<sup>[4,36-39]</sup> In addition, depression and sleep disorders are among the possible causes of fatigue.<sup>[40]</sup>

Brown et al.<sup>[8]</sup> reported that a single factor was identified for the 16-item scale and these items revealed a single factor explaining 58.2% of variance with factor loadings in the range 0.64 to 0.83. Although the results obtained in this study reflected the results of the standard scoring method, we also obtained very

close results. In addition, according to confirmatory factor analysis, the results of the TLI and the CFI were excellent, and the RMSEA result was acceptable. The PFS was compared with different generic fatigue scales in previous studies. When the original scoring system was used, the scale was found to have a strong correlation with the Rhoten Fatigue Scale in the British English version,<sup>[8]</sup> with Fatigue Severity Scale in American English<sup>[32]</sup> and Chinese versions,<sup>[31]</sup> and with the Functional Assessment of Chronic Illness Therapy-Fatigue scale in Swedish version.<sup>[34]</sup> A similar relationship between PFS and FSS was shown in the present study. The close relationship between the PFS and other generic fatigue scales suggests that the convergent validity of the PFS is good.

On the other hand, the current study has some limitations. First, it was a single-center study and there was no control group. Therefore, the results obtained may not be generalized. Second, we were unable to compare the fatigue severity between PD patients and controls. Therefore, further, large-scale studies including a control group are needed.

In conclusion, the PFS is a specific tool assessing fatigue in patients with PD. In the present study, we used the binary scoring method of PFS for ease of use. As a result, we found that the Turkish version of the PFS was culturally well-adapted with an acceptable validity and reliability.

#### Declaration of conflicting interests

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