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ORIGINAL ARTICLE

The Parkinson fatigue scale: an evaluation of its validity and reliability in Greek Parkinson's disease patients

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Abstract

Objective Fatigue is one of the most frequent and important nonmotor symptoms of patients with Parkinson disease (PD), affecting quality of life. Although, in some cases, it may be a severe and debilitating complaint, it remains relatively unexplored. The PFS-16 is a fatigue measure, specifically designed for PD patients. The aim of this study was to investigate the psychometric properties of Parkinson fatigue scale (PFS-16) in Greek PD patients.

Methods In total, 99 patients with PD were assessed. The following psychometric properties were tested: data quality, floor/ceiling effects, reliability (internal consistency, test–retest reliability), and construct validity. Construct validity was evaluated by examining correlations with other variables including other fatigue measures such as Fatigue Severity Scale (FSS) and the vitality scale (SF-VT) of SF-36. Moreover, assumptions were explored about "known" groups concerning fatigue.

Results The mean score for the PFS-16 was 2.95 (± 0.91); acceptability was good with negligible floor and ceiling effects. Results showed high internal consistency (Cronbach's alpha, 0.96) and test–retest reliability (ICC, 0.93). Strong correlations were observed between the PFS-16 and other fatigue (FFS and SF-VT) measures (rs = 0.77 and − 0.70, $p < 0.001$), revealing appropriate validity. Furthermore, predictions for "known" groups validity were verified.

Conclusion The Greek version of the PFS-16 showed satisfactory reliability and validity and thus can be regarded as a useful tool in assessing fatigue in PD.

Keywords Fatigue · Parkinson fatigue scale · Reliability · Validity

Introduction

Parkinson's disease (PD) is characterized by motor and nonmotor symptoms (NMSs). The latter are heterogeneous may precede the motor symptoms, and during the last decades, their important role is increasingly recognized [1].

Fatigue is a common and highly disabling NMS, usually underassessed, affecting significantly the quality of life, the activities of daily living, the ability to participate in social activities and causing psychological distress in PD patients [2–4]. It seems to present early in the disease course, even in the premotor period, independently of motor severity [2, 4], and it has been shown to have a high prevalence ranging between 32 and 58% [5–9]. The high diversity is due partly the different methods of diagnosis and the lack of a generally accepted definition and classification for fatigue, a fact that makes its measurement challenging.

Fatigue may be classified as peripheral and central [10]. Peripheral fatigue is defined as a physiological reaction to prolonged or intensive muscle activity while central fatigue is more subjective and is characterized by difficulty in initiating and sustaining mental and physical tasks that require self-motivation in the absence of motor or physical impairment [5, 10, 11]. Central fatigue may be further subdivided into physical and mental or cognitive.

A recent report from a multidisciplinary expert symposium suggested that PD fatigue should be better considered as a syndrome rather than a symptom and proposed the following

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definition: "a sense of exhaustion unexplained by drug effects, other medical, or psychiatric disorders, present for a defined period, and associated with other fatigue-related symptoms, such as reduced motivation and nonrestorative rest, or constraints on activities" [12]. However, this definition is still characterized by subjectivity, and as long as the pathophysiology of this disorder is not fully understood and no known biological markers have been identified yet, patient-reported outcome (PRO) questionnaires remain the main tools for screening, measuring, and comparing fatigue across studies.

The Parkinson fatigue scale (PFS-16) is the only fatigue scale which was specifically designed for evaluating fatigue in patients with PD [13]. The scale was developed for assessing the physical aspects of fatigue and their impact on the patient's daily function and deliberately excluded the emotional and cognitive features of fatigue, so as to avoid an overlap with other NMSs in PD. Moreover, the objective of the PFS-16 was to routinely be used in clinical practice and research studies [13, 14]. The scale has been "recommended" for screening and "suggested" for rating the severity of fatigue by a Movement Disorders Society Task Force on Rating Scales for PD [14]. The PFS-16 has been translated and validated to different languages and at present, there are Brazilian [15], Swedish [16], Chinese [17], and Turkish [18] versions.

The aim of this study was to translate it into Greek and culturally adapt the PFS-16 and to assess its psychometric properties.

Methods

Sample and data

This was an observational, cross-sectional study. Ninety-nine consecutive PD patients were recruited from the outpatient Movement Disorders Clinic of the "G. Papanikolaou" university hospital (3rd Department of Neurology of the Aristotle University of Thessaloniki). All patients were diagnosed according to the UK PD Society Brain Bank diagnostic criteria for idiopathic PD [19]. Exclusion criteria were as follows: other types of parkinsonism, other diseases than PD that could be related with fatigue (cancer, severe cardiomyopathy, severe anemia) and patients with dementia.

The research ethics committee of the Papanikolaou Hospital approved the study's protocol, and a signed informed consent in accordance with the Declaration of Helsinki was obtained from all participants.

Total daily L-dopa equivalent daily dose (LEDD) was calculated for all patients according to the previously described formula by Tomlinson et al. [20].

Test–retest

To evaluate test–retest reliability, a group of a convenience sample of the first 21 consecutive patients repeated the PFS-16 over a time interval of 14 days (time range 12–16 days) after the first evaluation.

Translation

We developed a Greek version of PFS-16 (PFS-16-G), following the internationally accepted procedures described in the literature for translation, cross-cultural adaptation, and validation of a patient-reported measure [21].

At first, we obtained permission to use PFS-16 from Dr. Richard G. Brown, the original author. Then, the questionnaire was translated into Greek by two independent translators, reconciled into one final Greek version, and translated back into English by a native speaker. Comparison of the back-translation and original versions of the questionnaire was performed and a final consensual translation was reached which was also proofread by the primary author of the original version.

Instruments

Fatigue was measured using the PFS-16 and the Fatigue Severity Scale (FSS).

PFS-16

The PFS-16 is a patient-rated scale that includes 16 items and each item score can range from 1 to 5 (1 = strongly disagree, 2 = disagree, 3 = do not agree or disagree, 4 = agree, and 5 = strongly agree). The PFS-16 originated from the statements of PD patients who experienced fatigue, and ratings are based on feelings and experiences over the prior 2 weeks [13].

In the original paper, two scoring approaches of the scale are described. In the first one, the total score is calculated as the mean response across all items and thus scores are ranging from 1.0 to 5.0. Higher scores correspond to more fatigue. The alternative scoring method dichotomizes scores according to the response: agree and strongly agree are scored 1 and all other answers 0. In this case, the total score can range from 0 to 16 with higher scores indicating more fatigue [13, 14]. Although the simpler binary scoring method was originally created for screening purposes, a recent study of the metric properties of the PFS-16, using modern psychometric methodology (Rasch analysis), did not recommend its use [22]. In this study, we used both scoring methods, and for the original one, a cutoff mean score ≥ 3.3 was applied for differentiating patients who perceived their fatigue to be a problem or not [13].

FSS

The FSS is the most commonly used fatigue scale in medical research and is the only "recommended" scale from the MDS Task Force for both screening and severity rating purposes [14]. It comprises nine statements concerning respondent's fatigue and patients are asked to rate their level of fatigue during the past week using a seven-point Likert scale (strongly disagree to strongly agree). Total FSS score is calculated as the mean score of the nine items ranges between 1 and 7. A cutoff score ≥ 4 generally indicates severe fatigue [23]. The FSS has shown a high reliability, validity, and internal consistency in both PD and non-PD populations [14, 24, 25]. The Greek-validated version was used [26].

Finally, other clinical assessment measures, in addition to fatigue scales, included the Mini Mental State Examination (MMSE) for evaluation of cognition, the Movement Disorders Society-Sponsored Revision of the Unified PD Rating Scale (MDS-UPDRS), and Hoehn and Yahr (HY) staging for disease severity [27, 28], the Hospital Anxiety and Depression Scale (HADS) for depressive symptoms and anxiety, the Parkinson's disease sleep scale (PDSS-2) for sleep quality, and finally the generic SF-36 and the disease-specific PDQ-8 for the assessment of health-related quality of life.

Statistical analysis

All statistical analyses were performed using SPSS v23.0 for Windows (Chicago, IL).

Normally distributed continuous variables were reported by mean and standard deviation (SD) otherwise by median and range and categorical variables were presented as counts and percentages. The normality of the data was assessed using Kolmogorov–Smirnov test. Respectively, for continuous variables, *t* test or the Mann–Whitney test was used for comparisons between groups and for categorical variables Chisquare test or Fisher's exact test. Nonparametric Spearman correlation analysis was used to evaluate the correlation between two variables. Spearman correlations of less than 0.30 were interpreted as weak evidence of validity, 0.30 to 0.50 moderate, and greater than 0.50 strong [29].

The following psychometric properties were assessed: data quality and acceptability, reliability (internal consistency and test–retest), and construct validity. Data quality were determined to be high if the percentages of missing responses for the various items were low (< 5%). Discriminatory power was assessed through floor and ceiling effects (percentage of the sample achieving the worst and best possible scores, respectively), which should be < 15% [30], as well as the overall skewness of the distribution of the scores (limits: − 1 and + 1). Reliability assessment included internal consistency and test–retest reliability. Internal consistency was evaluated using item-total correlations and Cronbach's coefficient alpha, both overall and with each item removed from the scale. Values > 0.70 were considered satisfactory [31, 32]. Additionally, the acceptance cutoff for item-total correlations was 0.30 [33]. Test–retest reliability was evaluated using Intraclass Correlation Coefficient (ICC) and acceptable values were ≥ 0.70 [31]. Convergent construct validity was investigated using Spearman's correlations coefficients. Strong relationship was hypothesized ($r \geq 0.50$), according to previous studies, between PFS-16 and FSS scores and between PFS-16 total score and PDSS2 and PDQ-8 [34, 35]. Also, a strong relationship was assumed with the vitality scale (SF-VT) of SF-36. Low to moderate association ($r < 0.50$) was predicted for PFS-16 with other clinical or demographic variables. Moreover, known-groups validity was explored, using criteria from the literature [8, 15, 16, 34, 35]. In particular, higher scores were expected to correlate with patients with longer disease duration, motor symptom severity, and patients with depressive symptoms. The threshold for statistical significance was assumed at $p < 0.05$.

Results

Demographic, clinical, and fatigue characteristics

Of the 99 individuals participating in the study, 72.7% ($n = 72$) were men, with a mean age of 62.75 ± 8.07 years and a mean disease duration of 8.26 ± 4.95 years. A summary of demographic and clinical data is presented in Table 1. The mean PFS-16 score of the entire sample was 2.95 (± 0.91) and clinically significant fatigue, according to the predefined cutoff score, was present in 38.9% of patients. The mean FSS score in this study was 4.00 (± 1.63) and 52.1% of participants had a score ≥ 4, indicating the presence of distressing fatigue. The agreement between instruments for classifying patients with clinically significant fatigue or not was at the 71.9% of the cases. However, a comparison of the two measures, using the McNemar test, showed a statistically significant difference between them, a finding that needs further investigation in future studies.

Data quality

All but one patient responded to the PFS-16 and thus the percentage of missing data was low (1.01%).

Acceptability or sensitivity

The original scoring method had low floor and ceiling effects (1%) while the binary scoring method had a higher floor (6.3%) and ceiling (3.2%) effects but within the accepted limits (< 15%). Also, skewness values were − 0.70 and + 0.285 respectively.

Table 1 Demographic and disease characteristics of PD patients

	Value
Gender *n* (%)	
Male	72 (72.7%)
Female	27 (27.3%)
Age (years)	62.75 ± 8.07
Education level *n* (%)	
≤ 6 years of education	18 (18.2%)
7–12	36 (36.3%)
> 12	45 (45.4%)
Disease duration (years)	8.26 ± 4.95
LEDD (mg/day)	450 (52–1578)
MMSE	29 (24–30)
PFS-16	2.95 (± 0.91)
FSS	4.00 (± 1.63)
PDSS 2	18.06 (± 14.67)
PDQ-8	15.63 (0–63)
SF-VT	60 (20–90)
Motor severity	
H&Y stage	2 (1–5)
MDS-UPDRS II	11 (0–46)
MDS-UPDRS III	24.34 (± 8.44)
HADS	
Anxiety	4 (0–15)
Depression	5 (0–14)

LEDD, levodopa equivalent daily dose; *MMSE*, Mini Mental State Examination; *PFS-16*, Parkinson fatigue scale-16; *FSS*, Fatigue Severity Scale; *PDSS 2*, Parkinson's Disease Sleep Scale 2; *PDQ-8*, Parkinson's Disease Questionnaire-8; *H&Y*, Hoehn and Yahr; *MDS-UPDRS*, Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale; *HADS*, Hospital Anxiety and Depression Scale

Reliability

The Cronbach's alpha for the original PFS-16 scoring method was 0.96 and for the binary method 0.92, both fulfilling the criterion of 0.70 (Table 2). When one item was deleted, alpha coefficient was reduced or remained unchanged in all cases, suggesting that all items contribute to the overall reliability of the scale. Additionally, all item—total correlations were strong (range, 0.490–0.823; Table 2), indicating that all items were measuring the same construct. However, for the binary method, item 1 showed low value close to the acceptable limits (0.305).

Test–retest reliability was assessed in a subgroup of patients ($n = 21$). The reproducibility was good for both methods with an ICC of original method 0.93 (95% CI, 0.81 to 0.97) and of binary 0.93 too (95% CI, 0.82 to 0.97).

Validity

The Spearman correlation coefficients between the PFS-16 scores with other PD-related variables are reported in Table 3. As anticipated, the PFS-16 total score had the highest correlations with FSS score ($r = 0.77$, $p < 0.001$) and SF-36-VT ($r = -0.70$, $p < 0.001$). Strong but slightly lower were the correlations with PDQ-8 ($r = 0.65$, $p < 0.001$) and PDSS2 ($r = 0.60$, $p < 0.001$). Regarding the known-groups validity, all assumptions were confirmed and the correlations were low to moderate but statistically significant. As far as it concerns sex, women were more fatigued (3.09 ± 0.88) than men (2.88 ± 0.92) but this difference was not statistically significant ($p = 0.32$).

Discussion

In this study, we examined the psychometric properties of the Greek version of PFS-16 in a sample of PD patients and our results showed to be a valid and reliable questionnaire. Moreover, our results were consistent with previous studies and in Table 4 are reported the similar validation studies of the PFS-16 in PD patients with different native languages.

The data quality of the PFS-16 was excellent, resulting in 98.9% data completeness. Overall, no floor or ceiling effects were observed in any of the scoring methods used. However, higher floor and to a lesser extent ceiling effects were present in the binary method. This finding was partly anticipated as dichotomization of possible responses leads to loss of information and thus reduced discriminatory power. Two previous validation studies found relatively large floor effects for the dichotomous method and beyond the accepted limits [16, 17]. Furthermore, Fu et al. reported large floor effects but within the limits in the polytomous original method as well. Our results were comparable and in line with the initial study by Brown et al. [13] and the remaining studies [15, 18]. The discrepancies observed among these validation studies could be partially attributed to sample differences, as samples with younger patients did not show significant floor or ceiling effects [17]. But, a second and more important justification could be the binary method itself, as it may have low sensitivity in detecting changes. A recent study, using modern test theory (Rasch analysis), showed inconsistent responses and concluded that there is no convincing evidence for the appropriateness of its use [22].

The PFS-16 showed high internal consistency reliability and similar to previous reports (Table 4). Cronbach's α was excellent for both methods (0.96 for polytomous original and 0.92 for binary dichotomized). Deleting an item from the Cronbach's α analysis, alpha values were minimally changed. Regarding the test–retest reliability, the ICC for the total score of the PFS-16 was also high (0.93) and in line with previous

Table 2 PFS-16 item descriptive statistics and reliability in both scoring methods

	Original scoring method			Binary scoring method		
n = 98	Mean (SD)	Corrected item—total correlation	Alpha (if item deleted)	Mean (SD)	Corrected item—total correlation	Alpha (if item deleted)
1. I have to rest during the day	4.21 (0.85)	0.490	0.96	0.90 (0.30)	0.305	0.92
2. My life is restricted by fatigue	3.25 (1.28)	0.758	0.96	0.53 (0.50)	0.651	0.91
3. I get tired more quickly than other people I know	3.54 (1.21)	0.737	0.96	0.68 (0.47)	0.634	0.91
4. Fatigue is one of my three worst symptoms	2.97 (1.30)	0.759	0.96	0.42 (0.50)	0.659	0.91
5. I feel completely exhausted	2.38 (1.21)	0.776	0.95	0.20 (0.40)	0.644	0.91
6. Fatigue makes me reluctant to socialise	2.57 (1.23)	0.743	0.96	0.28 (0.45)	0.565	0.92
7. It takes me longer to get things done because of fatigue	3.37 (1.31)	0.819	0.95	0.61 (0.49)	0.717	0.91
8. I have a feeling of heaviness	2.92 (1.27)	0.744	0.96	0.44 (0.50)	0.665	0.91
9. If I wasn't so tired I could do more things	3.43 (1.19)	0.765	0.95	0.60 (0.49)	0.617	0.91
10. Everything I do is an effort	3.21 (1.14)	0.672	0.96	0.51 (0.50)	0.577	0.92
11. I feel tired for much of the time	2.76 (1.14)	0.810	0.95	0.30 (0.50)	0.705	0.91
12. I feel totally drained	2.23 (1.09)	0.771	0.95	0.14 (0.46)	0.557	0.92
13. Fatigue makes it difficult for me to cope with everyday activities	2.82 (1.18)	0.805	0.95	0.37 (0.35)	0.671	0.91
14. I feel tired even when I have not done anything	2.37 (1.13)	0.736	0.96	0.20 (0.40)	0.589	0.91
15. Because of fatigue I do less in my day than I would like	3.24 (1.21)	0.823	0.95	0.54 (0.50)	0.752	0.91
16. I get so tired I want to lie down wherever I am	2.26 (0.99)	0.737	0.96	0.13 (0.34)	0.465	0.92
PFS total score	*Cronbach's alpha* = 0.96			*Cronbach's alpha* = 0.92		
	ICC = 0.93 (95% CI, 0.81 to 0.97)			ICC = 0.93 (95% CI, 0.82 to 0.97)		

SD, standard deviation; *ICC*, Intraclass Correlation Coefficient; *CI*, confidence interval

data (Table 4). Although our test–retest interval was long enough (time range 12–16 days) and results could be influenced by fluctuating motor and nonmotor symptoms [36], the choice to perform both assessments at the same hour of the day when theoretically patients were in similar on–off states could have been a possible factor for the excellent reproducibility. Moreover, the high ICC values might be partly influenced by a fact that our sample constituted by mostly male patients without advanced stages and thus with less fluctuating symptoms [37].

The PFS-16 showed good convergent construct validity, as revealed by highly significant correlations with FSS and the vitality subscale of the SF-36 (SF-VT) (Table 3). In particular, a strong association between the overall scores from PFS-16 and the FSS is a finding consistent with previous studies [17, 18, 38], although these scales are not measuring exactly similar aspects of fatigue, as PFS-16 was specifically designed to exclude nonphysical features. Moreover, Hagell et al. examined convergent validity of PFS-16 using another generic fatigue scale, FACIT-F, and appropriate construct validity was determined as well [16]. As expected, the PFS-16 demonstrated strong correlations with PDSS-2 and PDQ-8 scores. It is well known that sleep disturbances and quality of life are considered important factors consistently associated with fatigue [8, 39]. Finally, known-groups validity was verified. Patients with longer disease duration, motor symptom severity as assessed by MDS-UPDRS and H&Y scales and with depressive symptoms showed low to moderate association with PFS-16 scores. Our results did not show any significant association of fatigue with age and sex. In the literature, some studies demonstrated that females are in general more fatigued than males, but this result is not always present and data remain controversial [8, 15, 34, 40].

In our study, differences were observed between the two scoring methods. Although the binary method fulfilled the demanded criteria, there were discrepancies in the measurement of fatigue, a fact that enhances the previously reported data that its use may not be suggested in clinical practice or used at least with caution [16, 22]. On the other hand, the usage of original or polytomous method showed excellent psychometric properties. Taking into account that the PSF-

Table 3 Correlations of the total score of the PFS-16 with various Parkinson's disease-related variables

Variables	Spearman's correlation coefficient	*p* value
Age	−0.14	0.892
Disease duration	0.36	< 0.01
LEDD (mg/day)	0.28	< 0.01
MMSE	−0.17	0.140
FSS	0.77	< 0.01
PDSS 2	0.60	< 0.01
PDQ-8	0.65	< 0.01
SF-VT	−0.70	< 0.01
Motor severity		
H&Y stage	0.42	< 0.01
MDS-UPDRS II	0.59	< 0.01
MDS-UPDRS III	0.38	< 0.01
HADS		
Anxiety	0.47	< 0.01
Depression	0.49	< 0.01

LEDD, levodopa equivalent daily dose; *MMSE*, Mini Mental State Examination; *FSS*, Fatigue Severity Scale; *PDSS 2*, Parkinson's Disease Sleep Scale 2; *PDQ-8*, Parkinson's Disease Questionnaire-8; *H&Y*, Hoehn and Yahr; *MDS-UPDRS*, Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale; *HADS*, Hospital Anxiety and Depression Scale

16 is recommended for screening fatigued PD patients, it is salient that the questionnaire fulfills this target [14].

Finally, in this study, we have followed the recently published recommendations by Kluger et al. of fatigue measurement in PD [4]. Specifically, there was the statement of a clear definition and taxonomy; fatigue was distinguished from related symptoms, using validated instruments with the exception of apathy, secondary causes of fatigue were in the exclusion criteria and an accepted cutoff point was used for determining clinically significant fatigue. The application of the above criteria could eliminate some methodological issues that are often present and constitute confounding factors in PD-related fatigue research.

Limitations

The current study has some limitations. Firstly, the data were obtained from only one tertiary hospital and they may not be fully representative of the overall PD population in Greece. Secondly, the sample consisted predominantly of male patients and there was a relatively low representation of patients in the advanced stages of the disease. Also, according to the exclusion criteria, cognitively impaired patients were not assessed and thus the generalizability of the results is restricted. Finally, only classical psychometric methods were used for the validation of PFS-16.

Table 4 Psychometric properties of PFS-16 in previous and current studies using the original scoring method

				Data Quality	Sensitivity	Reliability			Validity					
									Disease severity				Fatigue scales	
Validation study	Year	Language	Age	Missing values (%)	Floor/ceiling effects (%)	Item—total correlation (min–max)	Cronbach's α	ICC	H&Y stage	UPDRS III	MDS-UPDRS III	FSS	FACIT-F
Grace et al.	2007	American English	71.7 (1.4)	—	—	—	0.97	—	—	—	—	0.84^{***}	—
Kummer et al.	2011	Brazilian	56.9 (10.3)	0	0/0	0.37–0.79	0.94	—	0.39^{***}	0.44^{***}	—	—	—
Hagell et al.	2012	Swedish	60.0 (6.7)	—	0/0	0.52–0.87	0.96	0.93	—	$< 0.18^{NS}$	—	—	0.89^{***}
Fu et al.	2017	Chinese	62.8 (9.6)	0	5.21/0.90	0.62–0.87	0.97	0.94	0.24^{**}	—	0.20^{NS}	0.87^{*}	—
Ozturk et al.	2018	Turkish	63.0 (9.8)	0	0/0	0.72–0.91	0.97	0.89	0.17^{*}	0.20^{*}	—	0.72^{***}	—
Current study	2018	Greek	62.8 (8.1)	1.01	1/1	0.49–0.82	0.95	0.93	0.42^{**}	—	0.38^{**}	0.77^{**}	—

NS, non-significant, $^{*}p < 0.05$, $^{**}p < 0.01$ ***, $p < 0.001$

ICC, Intraclass Correlation Coefficient; *H&Y*, Hoehn and Yahr; *UPDRS*, Unified Parkinson's Disease Rating Scale; *MDS-UPDRS*, Movement Disorder Society-sponsored revision of the Unified Parkinson's Disease Rating Scale; *FSS*, Fatigue Severity Scale; *FACIT-F*, Functional Assessment of Chronic Illness Therapy-Fatigue

Conclusion

Overall, PFS-16 demonstrated good reliability and validity and it could be a useful and feasible instrument for the assessment of fatigue in patients with PD in clinical practice and research studies.

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