Original Article

Psychometric Properties of the Persian Version of the Fatigue Impact Scale (FIS-P) in Patients with Multiple Sclerosis

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Objectives: This study was designed to evaluate the psychometric features of the Persian version of the Fatigue Impact Scale (FIS-P) tool when used in Iranian MS patients.

Methods: 140 MS patients and the equivalent number of healthy controls completed the following assessments: FIS-P, Fatigue Severity Scale (FSS), SF-36 questionnaire and the Mini-Mental State Examination (MMSE).

Results: A significant inverse correlation between FIS and the quality of life (SF-36 assessment tool), as well as a positive and significant correlation with the FSS were noted. The Intraclass Correlation Coefficient (ICC) values for the inter-rater reliability for the physical, cognitive, and social sections and the whole questionnaire were 0.89, 0.86, 0.95 and 0.98, respectively. The FIS Persian version was shown to possess a high reliability (with a Cronbach's alpha of 0.953). Likewise, the ICC values for the test-retest reliability were 0.86, 0.87, 0.92 and 0.93 for the physical, cognitive, social subscales and the whole questionnaire, respectively. This suggested a high reliability for the FIS-P.

Discussion: With a proper validity and reliability, the Persian-version of FIS retains the capability for being used in the assessment of fatigue and evaluation of the treatment and rehabilitation effects on fatigue-related symptoms among Persian-speaking patients with MS.

Keywords: Multiple Sclerosis; Fatigue, Fatigue Impact Scale; Psychometric; Persian

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Introduction

Multiple sclerosis (MS) is a challenging, progressive, and disabling neurological disease in young adults, mainly caused by autoimmune processes involving the myelin sheath. Depending on the location, size, and the time course of the sclerotic plaques and CNS lesions, the clinical manifestations of MS vary and may include motor, cerebellar, brain stem, sensory, visual, sphincteric, as well as cognitive insufficiencies and behavioral disorders (1). Fatigue is the most troublesome symptom and is a common complaint in MS patients (50-95%) (2-8), restricting patients' work and social communications (4,9-17), activities of daily life and lifestyles (7,18,19), as well as affecting their mental and psychological wellbeing (20,21). According to the Multiple Sclerosis Council Practice Guidelines (1998), fatigue is defined as a subjectively perceived compromise in physical and or mental energy which interferes with common and desired activities (13,22,23). Given its unknown etiology, the assessment and management of fatigue seem to be difficult (24,25). Meanwhile, due to the importance of fatigue in patients' functional and performance

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status, and its widespread presence among MS patients, access to an accurate qualitative and quantitative fatigue assessment tool in the assessment and management of its symptom is required (7,26,27). Access to such a tool would enable clinicians and researchers to more accurately evaluate the effects of treatment interventions on fatigue control. To our knowledge, the translated and culturally adapted Persian version of the FIS has not yet been assessed for validity and reliability. The current study was conducted to assess this tool. Some of the most popular examples of such tools include: Fatigue Impact Scale (FIS) (28), Fatigue Severity Scale (FSS) (29), Modified Fatigue Impact Scale (MFIS) (29), Fatigue Descriptive Scale (FDS) (30), and the Daily Fatigue Impact Scale (DFIS) (31) tests which have been applied in MS patients. FIS and FSS are the most common and accurate tests used both in research and clinical settings worldwide (7,19).

FIS (Fisk et al.) was first used to assess the impact of fatigue on daily life activities in MS patients (13,32,33). FIS is one of the most commonly used self-reported questionnaires with stronger psychometric features and a greater sensitivity, compared to other fatigue indicators (7). This tool was applied to evaluate fatigue in stroke, brain concussion, poliomyelitis, chronic fatigue syndrome, lupus and hepatitis patients (13,32,33). According to Fisk and his colleagues, the impact of fatigue on activities could be more sensitively assessed through FIS rather than simply asking the patients some fatigue-related questions (7). The test comprises 40 questions assessing the fatigue-related limitations in the patients' performance within the cognitive (10 questions), physical (10 questions), and social activity (20 questions) domains (4,7,34). Studies carried out in different languages such as American English (correlation coefficient of 0.68-0.85) (7), Turkish (correlation coefficient of 0.93 and the Cronbach's alpha of 0.97 and 0.91 for the whole test and sub-groups, respectively) (4), Hungarian (correlation coefficient of 0.85 and Cronbach's α of 0.98) (2) and French (Cronbach's α of 0.80 and correlation coefficient of≥0.70) (35) have demonstrated a strong reliability and internal consistency for FIS. However, the purpose of this study is to determine whether measuring the effects of therapeutic interventions on fatigue control in MS patients may be possible using a validated questionnaire in a local language. The current investigation attempted to develop the Persian version of FIS (FIS-P) and to assess its validity and reliability when administered to Persian-speaking patients with MS.

Methods

Design of study - This cross-sectional investigation evaluated the psychometric features of the Persian equivalent of the FIS (FIS-P) in Persian-speaking MS patients.

Preparing the FIS-P -Following an agreement with the institute where FIS originated (the French research institute of MAPI), the questionnaire was translated using the recommended forward-backward translation method. The process of finding equivalents for obtaining a fatigue assessment tool which is reliable in terms of clarity and ease of understanding was carried out according to the PRO (Patient Reported Outcomes) measures during the whole process of forward translation, backward translation, and patient-testing (34). Throughout the preparation process, the institute of origin (MAPI) was updated with the progress reports. Finally, the translated questionnaire was pre-tested and tested on patients to ensure if the content was fully understandable and the equivalent terms used in the translated version were correctly perceived.

Participants-This study enrolled 140 definite MS patients, as well as 140 healthy controls that were matched for age, sex, parental status and education. Patients were recruited amongst those registered and referred to the Tehran MS Society. This center is a governmental association considered as the referral center for MS patients across Iran (Table 1). Inclusion criteria in healthy subjects were: aged 18-50 and able to read and write with adequate cooperation. Exclusion criteria included: overt documented mental or psychiatric problems, regular hypnotics, anti depressive or antipsychotic use or addiction, history of chronic fatigue syndrome or symptoms of a chronic medical illness with a possible impact on fatigue and other fatigue-causing diseases. In the patient group, inclusion criteria were: definite MS patients according to McDonald 2010 criteria, aged 18-55, MMSE score≥21 and FSS≥4. The exclusion criteria in the patient group were: MS in relapse, taking anti-fatigue medications such as amantadine during the test period (unless discontinued at least 24 hours prior to the test) and any acute or chronic physical or mental illnesses. Cases and control subjects were enrolled in the study over a time course of recruitment. Based on such a consecutive sampling method, only the patients who fulfilled the inclusion criteria were recruited. Through this approach, a total of 140 cases as well as 140

control participants entered the study with their data finally analyzed. Our strategy was to enroll highly cooperative cases that fulfilled the inclusion criteria.

The ethical protocol of this study was based on Declaration of Helsinki. The whole process was approved by the institutional review board and was assigned the ethics code (1/d/320/349,2011-2012). Informed written consent forms were signed by all participants prior to enrollment. Participants were reassured that all evaluation in this study is non-invasive and causes no harm. Each subject could waive their continuation at any point during the study. Patients were informed about the significance of fatigue in their quality of life before being asked to participate in the study. All questionnaires and related documents remained anonymous throughout the study. Incomplete questionnaires were disregarded.

Assessment Tools - Fatigue Impact Scale (FIS): This tool was primarily designed to assess the impact of fatigue on daily activities (Fisk, 1994). The scale consists of 40 items in 3 domains: physical (10 items), cognitive (10 items) and social (20 items) (4,7,36). It is rated on a scale of 160 points, where higher scores indicate more fatigue (19).

-Fatigue Severity Scale (FSS): This scale rates individual perception of fatigue using 9 questions (19). Participants rate the questions from 1 to 7, with grade 1 meaning strongly disagree and 7 meaning strongly agree. By totaling the grades, a higher score indicates a more significant effect of fatigue on the individual's life. The validity and reliability of the Persian version of this scale was affirmed by Azimian et al. (5). - Short Form Health Survey (SF-36): This tool was designed to measure the quality of life of patients and healthy individuals. SF-36 is currently the most widely used tool to measure quality of life (37). The validity and reliability of the Persian version of this scale was assessed by Montazeri and colleagues (38).

-Expanded Disability of Status Scale (EDSS): This tool was designed by Kurtzke in 1983 to assess the degree of neurological impairment in MS patients. The scale is used to evaluate the pyramidal system, the cerebral, cerebellar, brain stem, sensory and visual systems. With a scale of 0-10, higher points indicate more disability. This assessment is performed by a neurologist (1,39).

Test administration-Having received the MAPI institute's approval, the Persian version of the tool was developed. The final version of this questionnaire is registered and currently available on MAPI Research Institute's website at http://www.mapi-trust.org. Following necessary explanations on the purposes of this research and how to answer the questions provided, the finalized questionnaires were administered to the enrolled subjects. In addition to FIS-P, other tools were administered. These were the SF-36 test to assess the participants QOL, the Expanded Disability Status Scale (EDSS) to measure the scale of participants' disability and the MMSE questionnaire to screen for cognitive ability.

Statistical analyses-The authors applied the Spearman correlation coefficients (for convergent validity), U Mann-Whitney (for divergent validity), Intraclass Correlation Coefficient (ICC) (for inter-rater reliability and test-retest reliability) and Cronbach's alpha coefficients (for internal consistency) in SPSS 17.0 (Statistical Package for the Social Sciences). A p-value of less than 0.05 was considered significant.

Results

Demographic and clinical characteristics of the two study groups are summarized in table (1) and (2), respectively

Table 1. Demographic data of patients with multiple sclerosis (n=140) and healthy adults (n=140)

variable		Patients with MS (n=140)		Healthy adults (n=140)		p-value
		N	Percent	N	Percent	
gender	Male	26	18.6	26	18.6	1
	Female	114	81.4	114	81.4	
Marital status	Single	44	31.4	50	35.7	0.448
	Married	96	68.6	90	64.3	
Education	≥12 class	21	15	20	14.3	0.368
	12-14 class	59	42.1	46	32.9	
	16 class	51	36.4	64	45.7	
	≤18 class	9	6.4	10	7.1	

Most of the patients (n=115, 82.1%) had the relapsing-remitting type of the disease, while 7 patients (5%), 17 patients (12.1 %) and 1 patient (0.7%), had the primary-progressive, secondary-progressive and progressive-relapsing types, respectively. The FSS evaluation for fatigue revealed a score of 40.69, SD 15.34 for the patients and 26.15, SD 12.02 for the healthy group.

Table 2. Descriptive analysis of the medical features of the patients with multiple sclerosis (n=140) and healthy adults (n=140)

Variable	Patients with MS (N=140)		Healthy control (N=140)	
	M	SD	M	SD
MMSE	28.66	1.79	28.94	1.13
FSS	40.69	15.34	26.15	12.02
Disease duration (months)	67.62	61.7	-	-
EDSS	2.12	1.7	-	-

MMSE: Mini-Mental State Examination FSS: Fatigue Severity Scale EDSS: Expanded Disability Status Scale To determine the content validity, the FIS was administered to 10 occupational therapy faculty members. The content validity ratio (CVR) of each question was calculated. The average validity ratio of the questionnaire indicated the content validity index (CVI). The CVI for the whole questionnaire was 0.85.

Since the data were not normally distributed according to the Kolmogorov-Smirnov test, the U Mann-Whitney was used to compare of the means of the two independent groups and to determine their divergent validity. The mean scores and the standard deviations of the two groups in each subscale and the whole questionnaire are shown in Table 3. According to such findings, for all subscales as well as for the global FIS-P score, there were significant differences between the MS patients and the healthy subject group.

Table 3. The mean and standard deviation differences of Fatigue Impact Scale (FIS) scores of patients with multiple sclerosis and healthy adults

Subscales	Patients with MS		Healthy adults		p-value
	M	SD	M	SD	
Physical	18.892	7.924	7.528	6.244	<0.001
Cognitive	13.021	8.486	7.585	6.028	<0.001
Social	31.105	14.167	14.844	10.364	<0.001
Total	63.019	27.832	29.958	20.706	<0.001

To study the convergent validity of FIS, Spearman's correlation coefficient was used to find out how the scores obtained for the different subgroups of the questionnaire, and the total score of the questionnaire, were related to the different subgroups of the QOL test (SF-36) and the FSS questionnaire. These three parts, as well as the whole questionnaire, had an inverse and significant correlation with the QOL index and a positive and significant correlation with the FSS (Table 4).

Table 4. Spearman's correlation coefficient of the Persian version of the FIS with the SF-36 and FSS (convergent validity)

scales	subscales	FIS			Total
		Physical	Cognitive	Social	
		r	r	r	r
SF-36	Phys F	-0.672**	-0.372**	-0.576**	-0.603**
	Role P	-0.628**	-0.483**	-0.626**	-0.646**
	Pain	-0.429**	-0.391**	-0.396**	-0.445**
	Gen H	-0.606**	-0.489**	-0.576**	-0.615**
	Vitality	-0.563**	-0.531**	-0.578**	-0.623**
	Soc F	-0.458**	-0.411**	-0.558**	-0.539**
	Role E	-0.444**	-0.36**	-0.565**	-0.516**
	Men H	-0.428**	-0.538**	-0.538**	-0.567**
FSS		0.682**	0.528**	0.636**	0.677**

r= Correlation Coefficient Spearman's rho **Correlation is significant at the 0.01 level (2-tailed)

The inter-rater reliability was determined by a random selection of 20 patients and was calculated by ICC. As outlined in table (5), the ICC values for physical, cognitive, and social domains, and the whole test, were 0.89, 0.86, 0.95, and 0.98, respectively.

Table 5. The inter-rater and test-retest reliability for the sub-groups of the FIS-P

Subscales		ICC	95% Confidence interval	p-value
Physical	Inter-rater	0.89	0.74-0.95	<0.001
	Test-retest	0.86	0.69-0.94	<0.001
Cognitive	Inter- rater	0.86	0.69-0.94	<0.001
	Test-retest	0.78	0.53-0.90	<0.001
Social	Inter- rater	0.95	0.89-0.98	<0.001
	Test-retest	0.92	0.82-0.97	<0.001
Total	Inter- rater	0.98	0.97-0.99	<0.001
	Test-retest	0.93	0.83-0.97	<0.001

**ICC: Intra-class Correlation Coefficient

The test-retest reliability was also determined by the random selection of 20 patients and was calculated by ICC. In Table 6, the ICC values for the physical, cognitive, and social sections and the whole questionnaire were 0.86, 0.78, 0.92, and 0.93, respectively. The Cronbach's α was 0.953. This demonstrates a similarly high reliability for FIS-P (Table 5).

Discussion

In recent years, the use of optimized measurement scales to evaluate the effects of disease as well as the impact of treatment and rehabilitation on the outcome has gained much attention (40,41). Fatigue is one of the most common, and at the same time most disabling, symptoms of MS which negatively affects the patients' quality of life (13). In order to provide patients with instructions and guide them through their fatigue management, a quantitative measure such as a valid questionnaire is needed (13,42). Furthermore, this quantification may assist health care professionals to efficiently plan treatment strategies to reduce fatigue-related symptoms (5). Nevertheless, such tools have mostly been used in clinical trials and research (33,36). Experienced translators contributed to the preparation of the final draft of the FIS-P. At the same time, we sought opinions from 20 MS patients to ensure the clarity of all translated terms and statements. For instance, in item number 10, despite the clarity of the term "clumsiness", this term was changed to "slow and uncoordinated movement". Since some participants, and females in particular, were unemployed, response to item 28 (financial resources) remained optional (there were 11 missing responses for this item). Moreover, as indicated by Fisk et al., the "sexual activity" item should also be adjusted to cultural frameworks (61 males waived responding to this item). Similar to what was observed by Fisk et al. (32) and Armutlu (4), this item was mainly answered by married individuals in our study. Our results are in line with those achieved in Mathiowetz's research, which confirmed that although the structures of the FSS and FIS differ somewhat, and the two tests assess different aspects of fatigue (the severity of fatigue or its impact), they demonstrate a positive correlation (r=0.6). Furthermore, an average correlation is observed between the FIS and similar sub-groups of SF-36. Since these tools do not measure identical structures, a high correlation was not expected (7). Often, due to the severity of the disease, hand-tremors and nystagmus prevent the patients from completing the questionnaire. This gives rise to a need for a second party to read the questionnaire items to the patients and mark their responses. Because of this, the inter-rater reliability needs to be evaluated. Despite this need, inter-rater reliability was not tested in other studies (2,4,7). The coefficients obtained for the ICC were 0.89, 0.86, 0.95, and 0.98 for the physical, cognitive, and social sub-scales and for the whole questionnaire, respectively. In studies by Mathiowetz (7) and Losonczi (2), a test-retest reliability assessment was carried out after an interval of six weeks and three months respectively (during which the retest was possibly affected by the progress of the disease). However, in our study, a one-week interval was used, with the results obtained conforming with those of Armutlu et al. (4) indicating ICC values of 0.86, 0.78, 0.92, and 0.93 for the physical, cognitive, and social sub-groups, and the whole questionnaire, respectively. These values indicate an excellent reliability for FIS. Taken together, our ICC results demonstrated greater values than those obtained by Mathiowetz and Losonczi in the German version, while it was comparable with those of Armutlu et al. (2,4,7). Similar to the studies conducted by Mathiowetz, Armutlu, and Losonczi, our Cronbach's α obtained for FIS-P (0.953) suggested a high internal consistency of FIS (2,4,7). Since we did not have an appropriate tool to assess the convergent validity of the P-FIS, we used the FSS and similar sub-groups of SF-36 to evaluate their validity. This can be considered as a limitation of the current study. Keeping in mind the fact that fatigue is a

common and disabling symptom in various chronic and disabling diseases, it is suggested that FIS be normalized in other populations. In addition, there seems to be a possibility for validating the use of the modified version of this questionnaire as the Persian version of the Daily Fatigue Impact Scale (D-FIS). This can be used to track the daily changes in terms of fatigue-related symptoms in the course of chronic diseases such as MS, Parkinson's disease and hepatitis. In other words, one may utilize the currently validated FIS-P version in order to validate and standardize further questionnaires.

Like many other investigations, the current study was subject to some shortcomings. These limitations included the lack of access to a larger sample size to assess test-retest and inter-rater reliability, and the paucity of similar reports which would have allowed for evidence comparison with our findings. We had no option but to assess the convergent validity of FIS-P using the validated Persian versions of FSS and SF-36. On the other hand, recruiting 140 MS patients and 140 healthy controls allowed us to efficiently assess the content validity and inter-rater consistency of the test. This has not been evaluated so far and thus can be considered as a strongpoint.

Conclusion

Given the strong psychometric features of FIS as compared with other tools, and based on the results of the current and similar studies on its proper validity and reliability, the Persian version of FIS (FIS-P) is suggested as a useful and suitable tool for assessing fatigue. This tool may also be applied to study the impact of treatment and rehabilitation interventions on fatigue in Persian-speaking MS patients. The use of the FIS-P questionnaire in local research centers is therefore recommended.

Conflict of Interest-None declared. The authors have no conflict of interest.

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