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Cross-cultural adaptation, reliability and validity of the Turkish version of the Fear of Relapse Scale (FoR) in individuals with multiple sclerosis

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ABSTRACT

Objective: The study aimed to translate and cross-culturally adapt the Fear of Relapse Scale (FoR) into Turkish and determine its psychometric properties.
Methods: International guidelines were used for the translation and adaptation process. The patients were asked to fill the FoR, Intolerance of Uncertainty (IUS-12) and Depression Anxiety and Stress Scale (DASS-21). One week later, participants refilled the FoR. The test-retest reliability, internal consistency, and construct validity of the FoR were analyzed.
Results: A total of 101 MS patients (37.6 ± 10.0 years, 81.2% women) were included in the research. The test-retest reliability of the FoR was excellent (ICC:0.883; CI:0.64–0.92). The reproducibility of the items of the FoR ranged from 0.2 to 0.8. The Cronbach's alpha coefficient of the FoR was 0.914. The internal consistency of the items was ranged between 0.90 and 0.91 The relationship between FoR with IUS-12, DASS-21 (depression), DASS-21 (anxiety), DASS-21 (stress) was 0.609, 0.641, 0.648 and 0.631, respectively. The correlation coefficients were greater than 0.50 ($p < 0.01$).
Conclusion: The Turkish version of the FoR is a reliable and valid tool to measure relapse fear in patients with MS.

1. Introduction

Multiple sclerosis (MS) is a neurological disorder with symptoms including visual problems, balance deficits, gait disorders, spasticity, paresis, weakness, pain, loss of sensation, fatigue, cognitive disorders, sphincter problems, sexual dysfunction [1,2]. MS causes disability by constructing functional disability at different levels and reduces the quality of life of individuals with MS by affecting both their professional and social lives [3,4]. The progression of MS varies depending on the disease phenotype and many factors. MS phenotypes are divided into three subgroups: "Relapsing-Remitting MS (RRMS), Secondary-Progressive MS (SPMS), and Primary-Progressive MS (PPMS)" [5]. 80% of the MS population have RRMS.

Transient episodes of neurological disability called relapses occur in RRMS [6]. During a relapse, local autoinflammation and demyelination of the central nervous system (CNS) are observed; relapse can last for one day, the patient also reports an increase in symptoms [6,7]. Depending on the localization of the demyelinated lesion in the CNS, visual, motor, sensory, cognitive, and psychosocial functions may be impaired [6,8]. Fatigue was reported as the most common symptom of MS, with 58% of prevalence [9]. Depending on the course of the disease and disability in the relapse period, the health-related quality of life of individuals with MS is also adversely affected [10,11]. Functional problems are frequent in patients with MS. This situation causes anxiety because of the uncertainty that individuals cannot predict their future disability [12]. In Turkey, Kahraman et al. found that 44% of individuals with MS have anxiety [13]. Functional losses, uncertainty in the progression of the disease, and fear of relapse increase the stress level in individuals with MS [4,14]. Relapses in MS can lead to feelings of anxiety, anger, and guilt [15]. Individuals with RRMS cannot predict the relapse time, severity and consequences [12]. In addition, the rate of early relapses in MS is associated with increased disease activity and disability in the later period [12,16]. Therefore, relapses have been reported to be a prognostic factor in the severity and progression of MS [17,18].

Individuals with MS have a fear of increased disability and feel

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anxiety during the relapse stage because of the unpredictability of the relapse [12,19].

The patient-reported outcomes revealing the psychological effects of MS are insufficient [12,20]. "Hospital Anxiety and Depression Scale (HADS)" can be used in the evaluation of depression and anxiety in individuals with MS [21]. On the other hand, "Beck Depression Scale (BDS) II" can be used to determine mood disorders in people with MS [22]. However, these PROs are insufficient to evaluate the psychological impact of MS precisely [20]. The fear of attacks in MS has been ignored in recent studies. However, the factors that make up the psychological dimension have an important place in improving the quality of life of individuals with MS [12,23]. Accordingly, the "Fear of Relapse Scale (FoR)" was developed to measure the fear of attacks in individuals with RRMS [12]. To our knowledge, the cross-cultural of the FoR has not been studied, including for the Turkish version. The present study aimed to analyze the psychometric properties of the Turkish version of the FoR in individuals with MS.

2. Materials and methods

2.1. Translation and cross-cultural adaptation

The methodological suggestions of "Guillemin et al. and Beaton et al." were considered for the translation and adaptation procedures [24,25]. The English version of the FoR was translated into Turkish with a committee including neurologists and physiotherapists who is native Turkish speaker. The expert committee synthesized the translations, considering the Turkish socio-cultural and dynamic specifications. Then, draft version was translated back into English by an expert translator whose mother tongue is English. The back-translated version was compared with the original version to create the final version of the FoR. Lastly, a pilot study was conducted with twenty cases to prove the comprehensibility of each questionnaire item.

2.2. Sample size estimation

The study's sample size was calculated with the G*Power software [26]. The effect size (0.3) was calculated over the "r^2" value (0.09) derived from the lowest coefficient in the development study [12]. Accordingly, a minimum of 88 individuals were required (a power and confidence interval were set as 0.90 and 0.05, respectively). In addition, considering the recommendation of at least 100 individuals for internal consistency analysis [27], a total of 101 individuals were included in the study. The required sample size for the retest with ICC was calculated as 26 (the expected ICC was set as 0.85, and the minimum acceptable ICC was set as 0.60) [28].

2.3. Study design

A cross-sectional and prospective study was conducted with MS patients (diagnosed with McDonald criteria) followed in the Ege University Faculty of Medicine Neurology Department. The permission for the translation for the Turkish version of FoR was acquired from the developer of the original questionnaire. The study was carried out in accordance with the ethical principles and the Helsinki Declaration. Informed consents of the patients were obtained. The study protocol was approved by the ethics committee of Ege University (No:21–9.1T/23). Participants were evaluated with the "Fear of Relapse Scale (FoR), Depression, Anxiety and Stress Scale (DASS-21), and Intolerance of Uncertainty Scale (IUS-12)". Then, after the one-week interval, FoR was refilled again to randomly selected 30 patients.

2.3.1. Fear of relapse scale (FoR)

FoR comprehensively evaluates the patients' fear of attacks and severity. Six items were removed from the 31-item initial version, and the final 25-item version was obtained. The FoR is scored with a 5-point Likert scale [12].

2.3.2. Depression, anxiety and stress scale (DASS-21)

DASS-21 was developed with a 42-item form. Afterwards, a 21-item form of the scale was created. The scale was developed to measure depression, anxiety, and stress symptoms in both clinical and healthy samples. There are seven items in total for each factor. The scale has a 5-point Likert-type response format, and the lowest score that can be obtained from each dimension is 7, and the highest score is 35. Increasing scores on the scale indicate an increase in symptoms. In the development study, the internal consistency coefficients for the sub-factors of the scale were found as follows: Depression,0.94; Anxiety,0.87 and Stress,0.91. The Turkish version was validated by Yıldırım et al. [29].

2.3.3. Intolerance of uncertainty scale (IUS-12)

IUS-12 consist of 12 items and two sub-dimensions. Cronbach's alpha was 0.84 for the total score. The Turkish version was adapted by Sarıçam et al. [30].

2.4. Statistical analysis

"IBM SPSS Statistics Version 25" computer package program was used for all statistical analyses. Descriptive statistical information was given as mean ± standard deviation (x ± SD) or %. "Kolmogorov-Smirnov/Shapiro-Wilk" tests were used to determine the homogeneity of the data distribution. The skewness and kurtosis coefficients were taken into account to ensure that the data had a normal distribution. "Intra-class correlation coefficient (ICC), standard error mean-standard error mean (SEM), and minimum detectable change (MDC)" was used to assess reliability. The relationship between FoR and other questionnaires was tested with the "Spearman Correlation coefficient" analysis. $P < 0.05$ was accepted as a statistical significance level. ICC and "Cronbach's alpha" values above 0.8 indicate high reliability, and a correlation coefficient above 0.50 indicates excellent validity [31–34].

3. Results

A total of 101 MS patients (37.6 ± 10.0 years, 81.2% Women) were included in the research. The mean body mass index of the patients was 24.3 ± 4.1 kg/m^2. The patients' mean MS duration was 6.7 ± 5.3 years. The relapse rate of the patients during the COVID-19 era was 33.7%. A vast majority of the patients were educated in university (62.3%). All patients' information related to socio-demographic and physical

Table 1
The socio-demographic and physical data of the MS patients.

n:101	Total
Age (years, mean±SD)	37.6 ± 10.0
Body mass index (kg/m^2, mean±SD)	24.3 ± 4.1
Gender (n, %)	
Women	82 (81.2)
Men	19 (18.8)
Duration of MS condition	6.7 ± 5.3
Relapse during COVID-19 era	
Yes	34 (66.3)
No	67 (33.7)
Education status (n, %)	
Elementary school	12 (11.9)
Secondary school	4 (4.0)
Senior high school	22 (21.8)
Bachelors or postgraduate	63 (62.3)
Marital status (n, %)	
Married	68 (67.3)
Single	33 (32.7)
Employment (n, %)	
Yes	47 (46.5)
No	54 (53.5)

SD: standard deviation, n: number of patients

characteristics is presented in Table 1. The mean questionnaire scores of the assessments are given in Table 2. The mean score of the FoR was 33.7 ± 16.5 for the total sample. The average FoR value for the test and retest (for 29 participants) was 33.1 ± 15.2 and 32.9 ± 21.9, respectively.

The test-retest reliability of the FoR total score was excellent (ICC:0.883; CI:0.64–0.92). The reproducibility of the items of the FoR ranged from 0.2 to 0.8. Most of the items had good to excellent reliability for the two-test session (with one-week interval) based on ICC (ICC>0.60). The internal consistency of the items and the total score of the FoR were excellent regarding the alpha values greater than 0.80. The Cronbach's alpha coefficient of the FoR was 0.914. The internal consistency of the items ranged from 0.90 to 0.91 (Table 3). Construct validity of the FoR was high considering the correlation coefficients. The relationship between FoR with "IUS-12, DASS-21 (depression), DASS-21 (anxiety), DASS-21 (stress)" was 0.609, 0.641, 0.648 and 0.631, respectively. All of the correlation coefficients were greater than 0.50 ($p < 0.01$) (Table 4).

4. Discussion

The present study was purposed to prove the reliability and validity of the Turkish FoR in patients with MS. Our results revealed that the Turkish version of the FoR is a reliable and valid tool to assess the fear of relapse in MS. The FoR was highly reliable in terms of both internal consistency and test-retest reliability. On the other hand, the construct validity results showed that FoR could be used in patients with MS.

Pain-related psychosocial disorders (e.g., fear of movement, pain catastrophizing and fear-avoidance behaviours are frequently observed in musculoskeletal system disorders. Particularly in patients with relapsing-remitting type MS, the patients' symptoms become more severe with the attacks that come in different periods of life. Therefore, activities of daily living and health-related quality of life may be affected. Depending on these situations or direct exposure, psychological disorders can reach anxiety and depression throughout life and become phobias. Therefore, the fear of attacks is one of the necessary conditions for MS patients. It is essential to evaluate the fear of attacks and manage the patients' symptoms and fear levels with behavioral psychotherapy models. In this respect, considering the lack of a standardized tool for evaluating patients, a comprehensive patient-centered fear of attack assessment tool developed by Khatibi presented a unique questionnaire to close the gap. To our knowledge, no study has revealed a language version of FoR [12]. We desired to perform a psychometric analysis of Turkish FoR that would inspire other language versions.

The individuals in our sample were individuals who were diagnosed approximately six years ago on average. During the COVID-19 period, 66.3 of the patients were a sample of individuals who had an attack, some actively working (46.5%). Khatibi et al. revealed the questionnaire's psychometric properties in 168 patients with relapsing-remitting MS in the development study of the FoR. Cronbach's alpha was 0.74 in the development study of the FoR. Cronbach's alpha was 0.74 in the development study of the FoR. Since the value was between 0.70 and 0.95, the alpha value was acceptable in terms of internal consistency. The alpha value in our study was 0.914, that is, relatively high than development study. The individuals in our sample may have more attack status and, therefore, a better understanding of the items. It should be noted that these are only estimates and the alpha value in both studies is sufficient to establish the internal consistency of the questionnaire. On the other hand, item-based alpha values were above 0.90 and below 0.95; which indicates acceptable limits of consistency [12,32,34].

Test-retest reliability was not specified with the ICC in the development study. Our study has an additional unique value in revealing the reproducibility of FoR. The questionnaire provided identical results after one week. The ICC of the FoR was 0.883. The low ICC coefficient in some of the items was noticed. Item 2, 3, 7, 17, 20, 27 and 28 were below 0.60 in ICC. Inconsistent results may be related with high levels of fear, which may not always be valid for all patients. A statement containing corticosteroids (item seven) may not represent all patients. The effect of relapse on postural stability and balance was covered in item 17. This statement may have caused inconsistent results due to our young sample, which is not generally having problems with the somatosensorial system. A relatively low ICC result may have been obtained since item 20 (bath), item 27 (headache), and item 28 (crying) may similarly vary according to each individual's other psychological and physiological states [12,31].

In our study, the construct validity of the FoR was calculated by comparing it with "IUS-12, DASS-21 (depression), DASS-21 (anxiety), DASS-21 (stress)": the coefficients were 0.609, 0.641, 0.648 and 0.631,

Table 2
The average score of the questionnaires.

n:101	Mean±SD	Range
FoR	33.7 ± 16.5	(6–79)
IUS-12	31.7 ± 10.4	(12–58)
DASS-21 (depression)	5.3 ± 5.2	(0–21)
DASS-21 (anxiety)	4.8 ± 4.6	(0–21)
DASS-21 (stress)	6.4 ± 5.3	(0–21)

SD: standard deviation, n: number of patients

Table 3
The reliability of the FoR in terms of test-retest and internal consistency.

	Test (Mean ±SD)	Retest (Mean ±SD)	ICC (95% CI)	α
Item 2	1.2 ± 0.8	1.2 ± 1.3	0.370 (−0.34 to 0.70)	0.912
Item 3	0.7 ± 0.7	1.3 ± 1.4	0.574 (0.09–0.80)	0.912
Item 4	1.9 ± 1.0	1.8 ± 1.3	0.693 (0.34–0.85)	0.909
Item 5	1.7 ± 1.0	1.1 ± 1.1	0.605 (0.16–0.81)	0.914
Item 6	0.7 ± 1.1	0.6 ± 1.2	0.825 (0.62–0.91)	0.913
Item 7	1.7 ± 1.4	1.4 ± 1.3	0.477 (−0.11 to 0.75)	0.914
Item 8	1.8 ± 1.5	1.6 ± 1.4	0.679 (0.31–0.84)	0.914
Item 9	1.5 ± 1.5	1.0 ± 1.3	0.670 (0.29–0.84)	0.908
Item 10	1.1 ± 1.2	1.2 ± 1.2	0.771 (0.34–0.80)	0.908
Item 11	1.0 ± 0.9	0.9 ± 1.2	0.768 (0.50–0.89)	0.909
Item 12	0.9 ± 1.1	1.2 ± 1.2	0.692 (0.34–0.85)	0.908
Item 13	0.6 ± 0.7	0.7 ± 1.2	0.794 (0.56–0.90)	0.911
Item 14	1.2 ± 1.1	1.3 ± 1.1	0.841 (0.66–0.92)	0.913
Item 15	2.3 ± 1.2	2.0 ± 1.1	0.825 (0.62–0.91)	0.915
Item 16	1.3 ± 1.0	1.2 ± 1.3	0.622 (0.19–0.82)	0.913
Item 17	1.5 ± 1.0	1.5 ± 1.2	0.594 (0.13–0.80)	0.907
Item 18	1.0 ± 0.9	0.8 ± 1.0	0.727 (0.41–0.87)	0.909
Item 19	2.0 ± 1.3	2.1 ± 1.3	0.822 (0.62–0.91)	0.910
Item 20	0.2 ± 0.5	0.5 ± 1.0	0.326 (−0.43 to 0.68)	0.913
Item 21	1.7 ± 1.1	1.4 ± 1.2	0.675 (0.30–0.84)	0.908
Item 22	1.0 ± 1.2	1.3 ± 1.2	0.784 (0.54–0.89)	0.912
Item 23	2.0 ± 1.2	1.9 ± 1.1	0.875 (0.60–0.93)	0.916
Item 25	0.7 ± 0.9	0.8 ± 1.1	0.607 (0.16–0.81)	0.908
Item 27	0.5 ± 0.7	0.7 ± 1.0	0.234 (−0.63 to 0.64)	0.910
Item 28	0.5 ± 0.7	0.5 ± 0.7	0.230 (−0.64 to 0.63)	0.911
Item 29	1.4 ± 1.4	1.6 ± 1.5	0.886 (0.75–0.94)	0.909
FoR total	**33.1 ± 15.2**	**32.9 ± 21.9**	**0.883 (0.64–0.92)**	**0.914**

n: number of patients, ICC: Intra-class correlation coefficient, CI: Confidence interval, α: Cronbach's alpha

Table 4
Construct validity of the MSIS-29.

n: 101	FoR	r
IUS-12	0.609 *	< 0.01
DASS-21 (depression)	0.641 *	< 0.01
DASS-21 (anxiety)	0.648 *	< 0.01
DASS-21 (stress)	0.631 *	< 0.01

respectively. All of the correlation coefficients were greater than 0.50 ($p < 0.01$). Khatibi et al. obtained a correlation coefficient of approximately 0.5 for FoR compared to the extended version of the IUS in the development study. Similarly, the comparison coefficient with FoR in DASS was around 0.5–0.6. FoR may represent patients' fear of attacks due to depression, stress, anxiety, and intolerance. There is no way to tell when the 'attack period', an uncertain state, will occur and end. The state of intolerance to uncertainty and subsequent forms of stress anxiety may proportionally represent the fear levels of patients [12,29,30,33].

Emphasizing the limitations contributes to the methodology of further studies. First, we could not analyze the questionnaire's responsiveness because there was no setting by which we could measure patients' response to long-term treatment. Second, we did not generate a homogeneous sample of individuals with relapsing-remitting MS. This situation was a shortcoming in reaching a sufficient number of samples. Therefore, it is also essential to evaluate only relapsing-remitting type MS and response to treatment in studies conducted to examine more psychometric properties of the Turkish version. Last but not least, investigating the construct validity of patients by comparing them with fear of falling or other disease-specific neuropsychiatric changes would further explain the psychometric properties of FoR.

5. Conclusion

Our results revealed that the Turkish version of the FoR is a reliable and valid tool to assess the fear of relapse in MS. The FoR was highly reliable in terms of both internal consistency and test-retest reliability. On the other hand, the construct validity results showed that FoR could be used in patients with MS as a perfectly valid tool.

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Ethical approval

The permission for the translation for the Turkish version of FoR was acquired from the developer of the original questionnaire. The study was carried out in accordance with the ethical principles and the Helsinki Declaration. Informed consents of the patients were obtained. The study protocol was approved by the ethics committee of Ege University (No:21–9.1T/23).

CRediT authorship contribution statement

Fatih Özden: Conceptualization, Investigation, Methodology, Writing - original draft. **Mehmet Özkeskin:** Conceptualization, Methodology, Writing - original draft. **Nur Yüceyar:** Investigation, Writing - review & editing.

Declaration of Interest Statement

The authors report no conflicts of interest and certify that no funding has been received for this study and/or preparation of this manuscript.

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