

## Psychometric Properties of the Persian Version of the PARADISE-24 Questionnaire

### Abstract

**Background:** Patients with multiple sclerosis (MS) suffer from a wide range of psychological problems. Application of a valid and reliable tool for psychosocial assessment is required for Iranian patients. The aim of this study is to determine the psychometric properties of the Persian version of the PARADISE-24 questionnaire in Iranian patients with multiple sclerosis. **Methods:** One hundred and thirteen multiple sclerosis cases were enrolled in this study. Participants were asked to answer the valid and reliable Persian version of the fatigue severity scale, social support scale, Pittsburg sleep quality index, and hospital anxiety and depression scale and translated version of the PARADISE-24 questionnaire. Twenty cases filed the questionnaire 2 weeks later to assess reliability. The intraclass correlation coefficient, Cronbach's alpha, correlation coefficients, and multiple regression analysis were used. **Results:** Mean age and mean duration of the disease were  $35.8 \pm 9.9$  and  $8.7 \pm 5.6$  years, respectively. The intraclass correlation coefficients ranged from 0.8 to 0.94 and Cronbach's alpha values (Cronbach's alpha was calculated as 0.91 for the whole questionnaire) were also significant. There were significant correlations between PARADISE-24 score and expanded disability status scale ( $r = 0.42, P < 0.001$ ), fatigue severity scale ( $r = 0.62, P < 0.001$ ), anxiety ( $r = 0.43, P < 0.001$ ) and Pittsburg sleep quality index scores ( $r = 0.46, P < 0.001$ ). Regression analysis by considering PARADISE-24 as dependent and other variables as independent showed that expanded disability status scale, fatigue severity scale, anxiety score, and Pittsburg sleep quality index were positive predictors of PARADISE-24 score. **Conclusions:** Persian version of PARADISE-24 questionnaire is a valid and reliable instrument for evaluating psychosocial aspects in patients with multiple sclerosis.

**Keywords:** Iran, multiple sclerosis, psychology, questionnaire

### Introduction

Multiple sclerosis (MS) is a complex disease which is characterized by inflammation and demyelination of the central nervous system (CNS).<sup>[1]</sup>

The natural course of the disease includes remissions, relapses, persistent disability, and constant progression.<sup>[2]</sup> According to the disease duration, extent and type of the disease, patients experience a wide range of psychological problems such as fatigue, depression, anxiety, impaired emotional intelligence, sexual dysfunction, pain perception, and sleep disturbances.<sup>[3-8]</sup>

Most MS cases are women in young adulthood age which experience distress after disease diagnosis as the disease impact psychological, social, and physical aspects of their lives.<sup>[9]</sup> Previously, it was discussed that patients with different types of brain disorders suffer from a

common pattern of psychosocial problems despite disease specific-symptoms and etiology.<sup>[10,11]</sup> To address similarity in psychological difficulties in cases with brain disorders, the PARADISE-24 (Psychosocial fActors Relevant to BrAin DISorders in Europe) questionnaire was developed.<sup>[12]</sup> It includes 24 questions assessing disease-related physical, psychological, as well as social problems which affected the patient's lives.

The total score is obtained by adding all scores and it should be transformed to 0–100.

The number of MS cases is increasing dramatically in Iran and disease-related disabilities resulted in experiencing a wide range of difficulties such as fatigue, depression, anxiety, sexual dysfunction, impaired quality of life, pain perception, and quality of sleep disturbances.<sup>[3-8]</sup> MS cases also suffer from social effects of MS on their personal life like stigma,

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marital problems as well as lack of social support.<sup>[13,14]</sup> The concerning issue is that single studies which were conducted previously, evaluated only one or two dimensions in different sample groups while there is a need for a comprehensive assessment for all cases. PARADISE-24 questionnaire provides this opportunity to describe the effect of a health condition such as MS on patients' life.

We designed this study to assess the psychometric properties of the Persian version of the PARADISE-24 questionnaire to apply for psychosocial evaluation in Iranian patients with MS.

## Methods

This cross-sectional study was conducted at MS research center of Sina hospital (affiliated hospital of Tehran University of medical sciences) between January and May 2019.

Inclusion criteria were:

MS diagnosis based on McDonald's revised criteria, and age older than 18.

All study participants were asked to fill informed consent forms.

Data regarding age, sex, education, marital status, disease duration, and expanded disability status scale (EDSS) was recorded for all included cases.

We contacted Alarcos Cieza and got his permission for psychometric analysis of the questionnaire.

By means of forward-backwards translation method, PARADISE-24 questionnaire was translated into the Persian language by a bilingual medical researcher. Afterwards, the Persian version translated into English by another bilingual medical researcher.

The two versions were compared by a neurologist. Afterwards, content validity was checked by five neurologists to evaluate if all questions were relevant and necessary.

Two independent patients valued each question as favorable (understandable and readable) or unfavorable (Face validity).

Content validity was evaluated by five independent neurologists.

Construct validity (convergent validity) assessed by calculating correlation coefficients between PARADISE-24 score and fatigue severity scale (FSS), social support scale, Pittsburg sleep quality index (PSQI), and hospital anxiety and depression scale (HADS).

The PARADISE-24 is a self-administered questionnaire on a three-point scale.

(None = 0, some = 1, a lot = 2). The total score ranges from 0 to 100, while higher scores indicate psychosocial difficulties following brain disorders.<sup>[15]</sup>

FSS is a 9-item questionnaire which is used to assess the severity of fatigue during the past week in various situations. Each question is graded as 1 to 7, where 1 indicates strong disagreement and 7 strong agreements. Summing up all scores will provide the final score. Valid and reliable Persian version was used.<sup>[16]</sup>

Perceived social support is a 12-item questionnaire which assesses different categories of support. Each item is graded from 1 (very strongly disagree) to 7 (very strongly). The final score is obtained by adding all scores. Valid and reliable Persian version was applied.<sup>[17]</sup>

Pittsburg Sleep Questionnaire Index (PSQI) consists of 19 questions including seven-component scores (sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction). Each component is scored from 0 to 3. The total score ranges from 0 to 21. The valid and reliable Persian version of this test was applied.<sup>[18]</sup>

HADS is a 14-item questionnaire that is used for depression and anxiety assessment (seven questions for depression and 7 for anxiety). Each item is graded on a four-point scale (0-3) consisting of a total score of 42. For each item (depression or anxiety) total score could be 21. We applied a valid and reliable Persian version.<sup>[19]</sup>

All data were analyzed using SPSS software version 22 (SPSS Inc., Chicago, IL, USA). Data are presented as mean  $\pm$  SD for continuous or frequencies for categorical variables. The intraclass correlation coefficient (ICC) was measured for repeatability, and ICC coefficient more than 0.70 was considered acceptable. Cronbach's alpha was calculated for the questionnaire to assess the internal consistency reliability. Cronbach's alpha coefficient  $\geq 0.70$  was considered as excellent reliability. KAPPA coefficient calculated for inter-rater agreement assessment. Correlation coefficients between PARADISE-24 score and other scores were calculated. Multiple linear regression analysis by considering PARADISE score as dependent and age, sex, marital status, duration of the disease, EDSS, FSS, PSQI, depression, anxiety, and social support scores as independent variables was done. (Normal distribution of the continuous variables was checked by means of normality tests and plots).

A *P* value of less than 0.05 was considered significant.

## Results

One hundred and forty cases were enrolled in this study while 113 completed questionnaires were collected (response rate = 80%). Mean age and mean duration of the disease were  $35.8 \pm 9.9$  and  $8.7 \pm 5.6$  years, respectively. Basic characteristics are summarized in Table 1.

The KAPPA for face validity calculated as 0.81. Cronbach's alpha was calculated as 0.91 for the whole questionnaire.

Mean scores of the questionnaires are summarized in Table 2.

There was a significant positive correlation between PARADISE-24 and FSS, anxiety, PSQI, and EDSS. The correlation coefficients between PARADISE-24 score and other variables are summarized in Table 3.

ICC for all items was equal to or more than 0.8 [Table 4].

Regression analysis showed that EDSS, FSS, anxiety score and PSQI were positive predictors of PARADISE-24 score [Table 5].

## Discussion

The aim of this study was to assess the validity and reliability of the Persian version of PARADISE-24

questionnaire which is used to evaluate psychosocial difficulties in patients with brain disorders.

The high ICC values of all questions show that the test-retest reliability of the Persian version of the PARADISE-24 questionnaire is valuable and significant.

The high Cronbach's alpha (0.91) for the whole questionnaire showed that the internal consistency of the questionnaire is acceptable.

The mean PARADISE-24 score was  $56.1 \pm 15.2$  which is higher than the score reported by Giovannetti *et al.*<sup>[2]</sup> They enrolled 80 MS cases and reported mean PARADISE-24 score of  $52.96 \pm 15.75$ . In their study, PARADISE-24 score had a significant positive correlation with EDSS and disability scale as well as a significant negative correlation with the quality of life score. In the current study, we found a significant positive correlation between PARADISE-24 and EDSS, FSS, anxiety, and PSQI scores. Disability which is assessed by means of EDSS in MS cases had been considered to have a positive correlation with fatigue, depression, anxiety,<sup>[5,7,20]</sup> and also a negative correlation with emotional intelligence, and quality of life.<sup>[3,21]</sup> In the current study, we found a significant positive correlation between EDSS and PARADISE-24 score and also the regression analysis demonstrated that EDSS was a positive predictor of PARADISE-24 score which indicates that patients with higher disability have more psychosocial difficulties according to their disease.

Fatigue is a common complaint in MS cases which interferes with daily activities and worsens during the day, impairing patient's quality of life.<sup>[7]</sup> The exact cause of MS-related fatigue is not clear while pain perception, sleep disturbances, and medications adverse effects are considered to play a role in MS-related fatigue.<sup>[7]</sup>

We found a significant positive correlation between FSS and PARADISE-24 scores as well as the positive predictive role for FSS. This could indicate that more fatigue severity, more psychosocial difficulties in MS cases.

One of the psychiatric comorbidities in MS cases which interacts with quality of life, clinical manifestations, and overall well-being, is anxiety.<sup>[22]</sup> Location of the plaques, disease course, and duration are considered as possible explanations for MS-related anxiety.<sup>[23]</sup> Our findings confirm that more anxiety experience, more psychosocial difficulties in MS patients.

Sleep problems are reported in more than 50% of MS cases<sup>[24]</sup> which can lead to fatigue, daytime sleepiness and impaired quality of life.<sup>[25,26]</sup> Poor sleep which is defined as PSQI >5 was positively correlated with PARADISE-24 and PSQI was a significant positive predictor of PARADISE-24 score, indicating that poor sleepers have more psychosocial difficulties.

**Table 1: Demographic characteristics of the patients**

Variable	Findings
Age (mean±SD)	35.8±9.9
Sex	
Female	87 (77%)
Male	26 (23%)
Marital status	
Married	60 (53%)
Single	53 (46.9%)
Occupation	
Employed	43 (38%)
Unemployed	70 (62%)
EDSS (median, IQR)	2 (1,3.5)

**Table 2: Mean scores of the questionnaires**

Questionnaire	Score (mean±sd)
PARADISE-24	56.1±15.2
FSS	5.4±2.4
HADS	
Anxiety	10.8±2.4
Depression	8.6±2.1
PSQI	5.7±3.8
Social support	62.3±15.7

FSS: Fatigue Severity Scale, PSQI: Pittsburg Sleep Questionnaire Index

**Table 3: The correlation coefficients between PARADISE-24 score and other variables**

Variables	PARADISE-24 (r, P)
Age	$r=0.2, P=0.02$
Disease duration	$r=0.15, P=0.16$
EDSS	$r=0.42, P<0.001$
FSS	$r=0.62, P<0.001$
Anxiety	$r=0.43, P<0.001$
Depression	$r=0.1, P=0.8$
PSQI	$r=0.46, P<0.001$
Social support	$r=-0.05, P=0.6$

ICC for all items was equal to or more than 0.8 [Table 4]

**Table 4: Results of test-retest in 20 patients who filled in the PARADISE-24 questionnaire twice**

Questions	ICC
How much of a problem did you have due to not feeling rested and refreshed during the day (e.g. feeling tired, not having energy)?	0.9
How much of a problem did you have with loss of interest?	0.92
How much of a problem did you have with your appetite?	0.94
How much of a problem did you have with sleeping, such as falling asleep, waking up frequently during the night or waking up too early in the morning?	0.85
How much of a problem did you have being so irritable that you started arguments, shouted at people or even hit people?	0.85
How much of a problem did you have with being slowed down or feeling as if things were moving too fast around you?	0.8
How much of a problem did you have with feeling sad, low or depressed?	0.88
How much of a problem did you have with worry or anxiety?	0.93
How much of a problem did you have with not being able to cope with all the things that you had to do?	0.88
How much bodily ache or pain did you have?	0.8
How much difficulty did you have in concentrating on doing something for 10 min?	0.8
How much difficulty did you have in remembering to do important things?	0.94
How much difficulty did you have in making decisions?	0.91
How much difficulty did you have in starting and maintaining a conversation?	0.94
How much difficulty did you have in walking a long distance such as a km (or equivalent)?	0.88
How much difficulty did you have in grooming or dressing, toileting or eating?	0.8
How much difficulty did you have in sexual activities?	0.92
How much difficulty did you have in staying by yourself for a few days?	0.9
How much difficulty did you have with looking after your health, such as eating well, exercising and taking your medicines?	0.88
How much difficulty did you have in initiating and maintaining a friendship?	0.88
How much difficulty did you have in getting along with people who are close to you?	0.8
How much difficulty did you have in your day-to-day work or school?	0.91
How much difficulty did you have with managing your money?	0.8
How much difficulty did you have in joining in community activities (for example, festivities, religious or other activities) in the same way as anyone else can?	0.92

**Table 5: Multiple linear regression to show that the predictor variables are adjusted**

	Unstandardized B	95%CI	P
Age	-0.09	(-0.1, 0.89)	0.4
Sex	-3.2	(-3.6, 1.21)	0.1
Marital status	-0.36	(-0.47, 1)	0.83
Duration of the disease	0.006	(-0.9, 0.004)	0.9
EDSS	1.9	(1.4, 2.1)	0.002
FSS	0.43	(0.2-0.6)	<0.001
Anxiety	1.3	(1.04-1.5)	0.002
Depression	0.89	(-0.1, 0.96)	0.08
PSQI	1.07	(1.03-1.5)	<0.001
Social support	0.016	(-0.01, 0.03)	0.82

In the current study, we did not find any correlation between social support and PARADISE-24 score which confirms Giovannetti *et al.* findings.<sup>[2]</sup>

Social support is important for MS cases as Wineman showed that unsupportiveness is related to poor adjustment in MS.<sup>[27]</sup> Other studies confirmed the positive effects of social support on quality of life of MS cases<sup>[28]</sup> as well as depressive mood in such individuals.<sup>[29]</sup>

The PARADISE-24 questionnaire was developed through horizontal epidemiology approach which evaluates the psychosocial difficulties following brain disorders. It was used

in different groups of patients with brain disorders such as migraine, seizure, stroke, dementia, and schizophrenia.<sup>[12]</sup> As it evaluates different domains, it could be a helpful questionnaire for psychosocial assessment in patients with brain disorders.

## Conclusions

The Persian version of PARADISE-24 questionnaire is a valid and reliable instrument for evaluating psychosocial aspects of MS patients.

## Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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## Conflicts of interest

There are no conflicts of interest.

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