

VALIDATION OF THE MULTIPLE SCLEROSIS QUALITY OF LIFE QUESTIONNAIRE-54 IN SLOVAKIA

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Authors' contribution:

- A. Study design/planning
- B. Data collection/entry
- C. Data analysis/statistics
- D. Data interpretation
- E. Preparation of manuscript
- F. Literature analysis/search
- G. Funds collection

Summary

Background. Quality of life assessment of patients with multiple sclerosis (MS) is not commonly performed in the Slovak Republic due to the unavailability of a validated Slovak version of a specific assessment tool.

Material and methods. The aim of this study was to transculturally adapt and validate the Slovak version of the Multiple Sclerosis Quality of Life Questionnaire (MSQoL-54). Psychometric analysis was performed by assessing reliability (Cronbach α), internal validation and external validation by measuring correlation with clinical factors such Expanded Disability Status Scale (EDSS) as well as other demographic factors. The questionnaire was validated on a sample of 298 patients with MS.

Results. Based on the results of the factor analysis, it can be concluded that the Slovak version of the MSQoL-54 questionnaire has comparable psychometric properties to the original version. External validation using EDSS showed a statistically significant inverse (negative) correlation on all components of the questionnaire.

Conclusions. The Slovak version of the MSQoL-54 questionnaire assessment tool can be used by Slovak healthcare professionals for a more comprehensive treatment of patients with MS.

Keywords: MSQoL-54, Slovakia, multiple sclerosis, validation, quality of life

Introduction

Multiple sclerosis (MS) is a chronic disease characterized by the pathological presence of inflammatory foci in the white matter in various regions of the central nervous system (CNS), demyelination, and the formation of glial scars. Worldwide, 2.8 million people suffer from this lifelong chronic disease [1]. According to the latest statistics from the National Centre for Health Information, 2,018 patients with MS were newly diagnosed in Slovakia in 2020, including up to 1,424 women. A total of 20,777 registered patients have been diagnosed [2]. A key diagnostic and prognostic phenomenon are the prevalence of morphological changes in different CNS locations and at different time periods of life. MS is characterized by

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alternating seizures and remissions with a gradual deterioration of health [3]. As the disease progresses, the patient becomes disabled and loses self-sufficiency in daily activities, causing feelings of hopelessness. The disease has a negative impact on the individual, the socioeconomic and emotional spheres, as well as on family members and society, which, in addition to therapeutic interventions, requires psychosocial approaches to help overcome problems related to the disease and its progression [4-6].

Several specific questionnaires are used to measure the quality of life (QoL) of MS patients, capturing specific problems related to the course of the disease [6-12]. One of the most used tools to measure and assess the QoL of MS patients is the Validation of the Disease-specific Multiple Sclerosis Quality of Life Questionnaire-54 (MSQoL-54) in Slovakia. This tool was originally developed in the USA in 1995 by Vickrey et al. [7] and has been transculturally adapted since. To date, the tool has been culturally validated in many languages (Italian, Turkish, Bosnian, Serbian, Slovenian, Hungarian, Indonesian, as well as for the needs of Canadian French) to overcome the language barrier while using the tool in clinical practice [13-17]. Good psychometric properties of the instrument have also been confirmed by many studies [18-20]. Even the short version of the questionnaire (MSQoL-29) has shown satisfactory psychometric properties in studies by Baker et al. [21] and Rosato et al. [22].

Aim of the work

The main aim of this research study was to linguistically and culturally validate the MSQoL-54 questionnaire in the Slovak language and to find out whether this instrument is helpful when assessing the QoL of patients with MS.

Material and methods

The validation study involved 298 patients diagnosed with MS, all of whom were treated at the Faculty Hospital in Prešov, Hospital with Polyclinic in Bardejov, and selected neurological outpatient clinics of the Prešov region (Slovakia) from December 2021 to May 2022. The inclusion criteria were as follows: minimum 18 years of age, diagnosed with MS according to the McDonald criteria, and written informed consent. Exclusion criteria were exacerbation of MS in the last three months, other chronic illness and/or psychiatric disorders.

The process of linguacultural adaptation of the MSQoL-54 questionnaire was carried out in the following phases: translation of the questionnaire into the target language, synthesis, adaptation and resolution of discrepancies within the language and culture, back-translation of the Slovak version into English, assessment by a panel of experts (physician, methodologist, researcher, language expert) in order to reach a final consensus and develop a preliminary version, a pilot study on a selected sample of patients with its validation and required corrections, submission of the questionnaire and references to the authors of the MSQoL-54 for the final validation process.

The internal reliability of the Slovak version of the MSQoL-54 was assessed for multi-item scales using Cronbach's alpha coefficients. Clinical validity was evaluated by comparison the averages of the two MSQoL-54 summary scores by Expanded Disability Status Scale (EDSS) score. Pearson's correlation coefficient (r) was used to examine the relationship between the summary score and the main clinical and demographic variables. To assess the construct validity of the dimensionality of the instrument, principal component analysis (PCA) with orthogonal Varimax rotation was planned. Preliminary analysis regarding data screening, testing of assumptions and appropriateness of selection was performed using the Kaiser Meyer-Olkin (KMO). The results were processed using the statistical SPSS 21 program and in the R pro-

programming environment using the lavaan and semTools libraries [23-26]. A Mann-Whitney U test was used to detect the exist of a significantly difference between two independent groups. Pearson correlations were used to determine statistically significant relationships between the study variables.

Results

A total of 298 respondents participated in the validation study. Demographically, women (63%) outnumbered men (37%) in our study sample. In terms of age, most were in the 30-39-year-old (26%) and 18-29-year-old groups (23%). The mean age of the entire research sample was 41.5 ± 11.1 years. Most of our respondents were undergoing immunomodulatory therapy (81%) and 18% were currently treatment-free. In terms of socio-demographic indicators, 65% were employed. When analyzing the EDSS results, our respondents scored 3.0 (standard deviation of 0.0-8.0) (Table 1).

Table 1. Research sample

Component	n	%
Gender		
Male	110	37
Female	179	63
Education		
Primary	0	0
Secondary without diploma	25	8
Secondary with diploma	208	70
University	65	22
Age (M\pmSD)	41.5\pm11.1 years	Min-Max: 18-66 years
18-29 years	69	23
30-39 years	76	26
40-49 years	59	20
50-59 years	55	18
60-65 years	39	13
Duration of disease (M\pmSD)	8.9\pm8.4 years	Min-Max: 1-30 years
1-4 years	148	50
5-9 years	76	25
10-14 years	30	10
15-20 years	30	10
21-30 years	14	5
Type of therapy		
Immunomodulatory	232	78
No therapy	66	22
EDSS (M\pmSD)	3.0 (0.0-8.0)	-
Presence of relapse within the last year (M\pmSD)	1.0 (0 - 3)	-
Employment		
Employed	185	62
Unemployed	113	38

Component	n	%
Level of self-care		
Self-sufficient	182	61
Partially self-sufficient	95	32
Non-self-sufficient	22	8
Cohabitation		
With partner	179	63
Without partner	110	37

Notes: n – number, M – mean, SD – standard deviation.

Principal components analysis was used to assess the construct validity of the dimensionality of the instrument (PCA) on 12 subscales with orthogonal Varimax rotation. Preliminary analysis regarding information screening, hypothesis assessment, and selection bias was carried out using the Kaiser Meyer-Olkin (KMO) statistic with respective values >0.5 and Bartlett's test of sphericity with $p \leq 0.05$. The KMO test and Bartlett's test were found to be statistically acceptable (>0.5) for subsequent use of PCA. The PCA results showed that only the first two components had eigenvalues greater than 1, accounting for 63.1% of the total variance. Hence, only these two components were retained in the analysis. The data for each of 11 MSQoL-54 subscales (50 items) with ≥ 3 items were Physical Health Composite (PCM) adjusted. In addition, in neither case was there a correlation between the residuals of the items >0.40 , thus meeting the assumption of local autonomy. The RI was ≥ 0.70 in 7/11 subscales. The RI of the remaining three subscales was lower: 0.69 (cutoff value) for Sexual Function, 0.63 for Social Function, and 0.62 for Health Perception. Yet, although the Sexual Function, Social Function, and Health Perceptions subscales had lower RI, they explored important dimensions of HRQoL for people with MS and were therefore retained in the questionnaire structure. According to the findings of the factor analysis, it can be concluded that the Slovak version of the MSQoL-54 questionnaire has comparable psychometric properties to the original version. Item analysis based on good correlation coefficients demonstrated the appropriateness of all items and showed statistically significant correlations of all items with their respective subscales excluding the item being analyzed. The remaining items statistically significantly correlated with their respective scales demonstrated the strength of correlations as $0.279 < r > 0.688$.

In general, a high reliability value was found in this study, which demonstrated that this tool is internally consistent. The validated questionnaire for the Slovak population shows a significant degree of reliability through the Cronbach α coefficient, as it has a Cronbach α value of 0.979 for the whole questionnaire and 0.78-0.97 for the individual subscales of the questionnaire (Table 2).

Table 2. Results of the reliability analysis of the MSQoL-54 questionnaire for individual subscales

Component	n	Number of items	Cronbach α	Cronbach α Vickrey et al. [7]
Physical Health	298	10	0.962	0.96
Physical Role Limitations	298	4	0.975	0.86
Emotional Role Limitations Emotional Problems	298	4	0.893	0.84
Pain	298	3	0.977	0.92
Emotional Well-Being	298	5	0.876	0.87

Component	n	Number of items	Cronbach α	Cronbach α Vickrey et al. [7]
Energy	298	5	0.930	0.84
Health Perception	298	5	0.920	0.85
Social Functions	298	3	0.897	0.75
Cognitive Functions	298	4	0.883	0.90
Health Difficulties	298	4	0.931	0.91
Sexual Functions	298	4	0.933	0.85
Change in Health	298	1	-	-
Satisfaction with Sexual Activity	298	1	-	-
Overall QoL	298	2	0.972	0.86

Notes: n – number.

The overall QoL scores (Table 3) of our respondents scored highest in the Cognitive Function (60.09), Social Function (59.09) and Pain (57.72) subscales. The worst scores were observed in the Overall QoL (29.33), Role Limitations due to Physical Problems (31.66) and Energy (39.03) subscales.

Table 3. Overview table – whole sample of respondents

Component	M	SD	Min-max
Physical Health	50.15	33.92	0-50
Physical Role Limitations	31.66	40.78	0-100
Emotional Role Limitations	52.12	46.60	0-100
Emotional Problems			
Pain	57.72	26.40	0-100
Emotional Well-Being	54.61	20.44	4-100
Energy	39.03	20.45	0-100
Health Perception	44.42	19.32	10-90
Social Functions	59.09	23.87	8-100
Cognitive Functions	60.09	25.65	5-100
Health Difficulties	54.06	26.32	0-100
Sexual Functions	42.42	22.50	0-100
Change in Health Status	55.55	33.62	5-100
Satisfaction with Sexual Activity	45.62	37.26	0-100
Overall QoL	29.33	30.16	0-100

Notes: M – mean, SD \pm – standard deviation.

External validity was estimated by testing the relationship of each component and composite score with the EDSS score. Scores on each dimension and domain of the MSQoL-54 were expected to be negatively correlated with the EDSS. Pearson (r) and Spearman (p) correlation coefficients were used to measure the

association of the composite score with clinical and demographic variables. Statistically significant inverse (negative) correlations were found between EDSS scores and all MSQoL-54 scales (Table 4). The most significant correlations were found between EDSS, Pain and Physical Health scores and also with the Total Physical Score ($p<0.001$). Correlations at the $p<0.01$ level were demonstrated in the areas of Role Limitations due to Physical Problems, Role Limitations due to Emotional Problems, Emotional Support, Energy, Social, Cognitive Function, Satisfaction with Sexual Activity, and Overall QoL. Statistically significant inverse (negative) correlations were found between disease duration and MSQoL-54 subscales at the $p<0.01$ level in the Physical Health, Social Function, Cognitive Function, and total Physical Health subscales. In other areas, we did not find significant correlations in our sample. Statistically significant positive correlations were found between the number of relapses and the MSQoL-54 subscales at the $p<0.001$ level in the Role Limitations due to Physical Problems, Cognitive Function, and Changes in Health Status subscales. At the significant level of $p<0.01$, positive relationships with increasing number of relapses in the Energy and Overall QoL subscales, and at the level of $p<0.05$ the Physical Health, Social Function and Health Problems subscales were confirmed. In other areas, we found no significant differences in our sample.

Table 4. MSQoL-54 and EDSS correlation results (Pearson correlations)

Component	EDSS		Duration of the disease	Number of relapses
	n	r	r	r
Physical Health	298	-0.685***	-0.356**	0.235*
Role Limitations due to Physical Problems	298	-0.522**	-0.181	0.530***
Role Limitations due to Emotional Problems	298	-0.385**	-0.530	0.171
Pain	298	-0.756***	-0.003	0.042
Emotional Well-Being	298	-0.440**	0.059	0.111
Energy	298	-0.426**	-0.106	0.506**
Health Perception	298	-0.211*	-0.021	0.032
Social Functions	298	-0.427**	-0.197**	0.320*
Cognitive Functions	298	-0.476**	-0.224**	0.752***
Health Difficulties	298	-0.342**	-0.195	0.295*
Sexual Functions	298	-0.352*	-0.054	0.152
Change in Health Status	298	-0.329**	-0.025	0.725***
Satisfaction with Sexual Activity	298	-0.377**	-0.069	0.023
Overall QoL	298	-0.301**	-0.152	0.552**
Physical composite score	298	-0.727***	-0.627**	-
Mental composite score	298	-0.576**	-0.376	-

Notes: n – overall number, r – Pearson's correlation coefficient, $p<0.05^*$, $p<0.0**$, $p<0.001***$.

In terms of the MSQoL-54 questionnaire scores and treatment for MS disease, we tracked the respondents' answers according to whether or not they were currently taking treatment for MS. The Mann-Whitney U test was used to determine the existence of a significant difference between two independent groups. In Table 5, we present a comparison of the statistics of all subscales; comparing the group of respondents taking treatment (n=232) and not taking treatment for MS (n=66). A significant difference was observed in the Change in Health Status subscale only, where respondents enrolled in treatment demonstrated better scores.

Table 5. Results of correlations between MSQoL-54 and disease treatment

Component	n	U	z	p
Physical Health	298	1677	1.92	0.053
Role Limitations due to Physical Problems	298	1777	1.51	0.093
Role Limitations due to Emotional Problems	298	1866	1.15	0.211
Pain	298	1965	0.71	0.595
Emotional Well-Being	298	2000	0.59	0.457
Energy	298	1898	0.64	0.551
Health Perception	298	1971	0.71	0.520
Social Functions	298	1721	1.75	0.078
Cognitive Functions	298	1721	0.45	0.651
Health Difficulties	298	2003	0.58	0.558
Sexual Functions	298	1789	1.46	0.465
Change in Health Status	298	1682	1.98	0.043*
Satisfaction with Sexual Activity	298	1577	1.51	0.365
Overall QoL	298	2100	0.18	0.785
Physical composite score	298	2548	0.12	0.231
Mental composite score	298	-0,376	0.33	0.442

Notes: n – number, (Mann-Whitney U test) p – statistical significance level, $p<0.05^*$, $p<0.01^{**}$, $p<0.001^{***}$.

Table 6 provides a comparison of all areas surveyed in terms of both genders. Based on our presented results, we can observe that Social Function were rated better by men than women. Significant differences between genders at the $p<0.05$ level were found in Role Limitation due to Physical Problems, Emotional Problems, Pain, and Sexual Functions in favor of males. In other areas, we did not observe statistically significant differences between the genders.

Table 6. Gender comparison summary table

Component	Men (n=110)		Women (n=179)		p
	M	SD \pm	M	SD \pm	
Physical Health	57.48	28.50	57.22	32.08	0.562
Role Limitations due to Physical Problems	28.85	24.6	36.72	32.02	0.032*
Role Limitations due to Emotional Problems	56.67	44.72	48.42	44.62	0.032*

Component	Men (n=110)		Women (n=179)		p
	M	SD±	M	SD±	
Pain	72.54	32.92	29.91	27.93	0.041*
Emotional Well-Being	51.2	19.73	52.1	20.01	0.856
Energy	46.40	16.6	41.17	21.1	0.315
Health Perception	46.50	21.97	47.15	19.76	0.502
Social Functions	64.42	18.88	62.90	24.58	0.544
Cognitive Functions	59.50	23.94	57.60	22.64	0.770
Health Difficulties	56.50	26.9	53.21	25.8	0.611
Sexual Functions	69.26	35.11	52.71	30.88	0.033*
Change in Health Status	57.58	17.9	56.09	20.06	0.856
Satisfaction with Sexual Activity	50.54	28.09	45.55	37.2	0.785
Overall QoL	43.75	22.76	42.2	38.52	0.842

Notes: n – number, M – mean, SD – standard deviation, p – statistical significance level, $p<0.05^*$, $p<0.01^{**}$, $p<0.001^{***}$.

Statistically significant inverse (negative) correlations were found between the respondents' age and the MSQoL-54 subscales at the $p<0.001$ level in the Physical Health subscale, and at the $p<0.01$ level in the Role Limitations due to Physical Problems, Social Functions, Pain, and Sexual Activity subscales. Statistically significant correlations were also found in the Change in Health Status domain at the $p<0.05$ level. In other areas, we found no significant differences in our sample (Table 7).

Table 7. Results of correlations between MSQoL-54 and age (Pearson correlations)

Component	n	r	p
Physical Health	298	-0.518	***
Role Limitations due to Physical Problems	298	-0.303	**
Role Limitations due to Emotional Problems	298	-0.070	-
Pain	298	-0.206	**
Emotional Well-Being	298	-0.080	-
Energy	298	-0.044	-
Health Perception	298	-0.012	-
Social Functions	298	-0.258	**
Cognitive Functions	298	-0.085	-
Health Difficulties	298	-0.005	-
Sexual Functions	298	-0.265	**
Change in Health Status	298	-0.179	*
Satisfaction with Sexual Activity	298	-0.117	-
Overall QoL	298	-0.094	-

Notes: n – number, r – Pearson correlation, $p<0.05^*$, $p<0.01^{**}$, $p<0.001^{***}$.

Discussion

MS is a nosologically heterogeneous entity with a variable clinical picture characterized by a spectrum of disorders of individual body functions with varying degrees of incapacitation of the patient. Patients need a special approach to deal with various interdisciplinary problems (e.g. voiding disorders, depression, anxiety states, cognitive disorders, chronic fatigue), and last but not least, they also need help and support in dealing with various social problems. In this context, the assessment of the quality of life of patients with SM becomes particularly important [26-28]. At present, it is not yet possible to cure the disease. Recently, the phenomenon of QoL has come to the forefront of many disciplines. The concept of QoL mainly encompasses issues of physical and mental health but is clearly multidimensional and affects different areas of a person's personality (physical, sexual, rational, emotional, religious, economic, occupational, familial, social and societal). What is also undeniable is the highly subjective nature of the patient's self-assessment of QoL, which stems from the unique personality setting of each individual and his or her ability to adapt to life circumstances, while the support of the patient's surroundings also plays an important role [22].

Subjective feedback provided by the patient enables the attending healthcare professional to improve cooperation with the patient and thus increase adherence to treatment by adapting to his/her legitimate requests. Another perspective on the course of the disease and the patient's QoL is the assessment by the companions and caregivers of the affected persons. These assessments very often differ from those of the patients themselves, and it is known that carers often rate QoL more pessimistically and, consequently, more poorly than the patients themselves [28]. In clinical practice, the current state of QoL assessment in patients with MS is characterized by considerable inconsistency and numerous differences in the use of assessment tools [6].

Acceptance of the questionnaire

The Slovak MSQoL-54 questionnaire was well accepted by our MS patients, with 95% of them having no problem completing it independently. This result does not differ from the results obtained from American, Italian, Turkish and Serbian patients with MS [14-16]. In our research, a small percentage of patients needed help and assistance from nurses to complete the questionnaire (29%) due to visual or fine motor impairments.

In this validation study, in which 298 respondents participated, all items were 100% completed and no items were missing. In other validation studies, there was a small number of patients who were uncomfortable and did not complete questions about sexual function and satisfaction with sexual function. In previously published similar studies, these questions have been a major source of missing data [15,16]. The mean time taken to complete the questionnaire was 16.2 ± 9.2 minutes, indicating that it was not a difficult task for the patients and that the questionnaire was easy to understand. Similar results have been found in other studies, where the mean time to complete the MSQoL-54 ranged from 11.8 to 30 minutes [12,14-16].

Reliability of the questionnaire

We found that the internal consistency of the subscales ranged from 0.75 for the Social Function subscale to 0.97 for the Pain subscale. The MSQoL-54 scales were reliable and performed at the required level in Bosnia and Herzegovina, as well as in the Brazilian and Turkish studies [14-16].

Construct validity of the questionnaire

In our study, CFA analysis of the 11 MSQoL-54 subscales showed overall good agreement. Based on the results of the factor analysis, it can be concluded that the Slovak version of the MSQoL-54 questionnaire has comparable psychometric properties to the original version. Only one study was published where a principal components analysis was conducted, namely the validation research of Stern et al. [18], who found differences between subscales and components observed only for Energy and Role limitation due to emotional problems. Conversely, the Health Perception and Social Function components were also classified into different domains compared to the original domain proposed by Vickrey et al. [7]. Such a result was not found in the study by Stern et al. [18]. The limitation of the research was the small sample size of respondents in this study.

External validity of the questionnaire

The overall assessment of individual subscales in our study indicates low perceived QoL among our respondents – patients with MS. Like the results found by Barbara Vickrey et al. [7], most of the subscales accounted for much of the variance in the results. The same was observed in the American study. However, all their scales showed minimum (0) and maximum (100) values. In this study, the domains of emotional well-being, energy, health concerns, and QoL generally had no minimum values (0) as they presented very low scores. This showed that these scores did not interfere with QoL that much compared to the others. Compared to the study by Vickrey et al. [7], our respondents scored lower in all subscales except the Physical Health subscale (PHC). The highest average score was recorded in satisfaction with social functions. That is, these areas revealed the strongest positive and negative effects in the studied sample. This was even more extreme for the follow-up values of the energy/fatigue and cognitive function scales.

The EDSS scores were significantly negatively correlated with all health status dimensions and subscales of the MSQoL-54 in our study. These correlations are similar and comparable to the validation studies conducted as well as the results of the study by Vickrey et al. [7]. PHC and MHC also showed significant correlation with EDSS. A Serbian validation study found that these domains were significantly correlated with patients' age, education, and occupation. The Hungarian validation study reported that the group of patients who had lower EDSS had better HRQoL scores in each scale. Solari et al. [14-16] also found a high correlation between both composite scores and age. Other factors in the QoL of patients with MS may also have an impact. A Hungarian validation study found that younger patients with a higher level of education, shorter disease duration and after the first attack or benign clinical form of the disease had a better QoL. QoL decreases rapidly in proportion to increasing EDSS. Ways of assessing the QoL of patients with MS are comparable in countries with a high incidence and prevalence of the disease. The relative satisfaction of patients reflects not only the level of healthcare provided in each country, but also the level, availability and cost of various social services and assistance. Patients report impaired mobility as the most important parameter a reduction in the ability to move independently has the highest correlation with a reduction in QoL. Up to 64-85% of MS patients have walking impairments, and the ability to move independently has the greatest impact on quality of life for people with both early and advanced MS, regardless of gender. Gait impairment is also the most common cause of reduced work productivity and/or job loss [12-14].

In this study, we found a correlation between the subscales of the MSQoL-54 questionnaire and other clinical and demographic factors such as age, disease duration, level of self-care, education, and the number of relapses in the past year experienced by the patients. The results of the Turkish study indicate that no significant correlation was found between the composite score and age, gender, education level, marital

status, and health insurance coverage in their representative sample of respondents [16]. Similar results were obtained in an Indonesian validation study [19].

In validation studies by Stern et al. [18], Estiasari et al. [19], and Čatić et al. [20], the MSQOL-54 questionnaire has indicated a significant association with severity of MS symptoms during the previous year, level of mobility, limitations in employment due to health problems, and hospitalizations during the previous year.

Conclusions

This is the first validation study of a specific QoL tool in a group MS patients in the Slovak Republic. Further evidence of construct validity can be supported by several different approaches of demonstration. The most important is a factor study – specifically looking at multidimensional constructs such as QoL measurement tools. Measuring individual areas of QoL provides a better interpretation of how the disease and its treatments translate into the daily life of an MS patient. It also helps to better understand preferences, expectations, and requirements in relation to the disease. These findings can be used in clinical practice to provide ongoing and follow-up care, as well as to improve patient adherence and self-care in the context of a comprehensive therapeutic regimen. When assessing the QoL of patients in Slovak studies, the use of generic tools for measuring the QoL of patients with MS is predominant. The use of specific tools, such as the MSQoL-54, for clinical and patient research purposes is recommended by experts and multinational organizations in the field of MS.

The limitation of our study was the selection of patients and the size of the cohort. The sample size was appropriate to the sample size requirements of the validation study (the number of questionnaire items, population). Due to the cross-sectional design of the study, longitudinal validity could not be observed. Therefore, further research is needed in the future to test the sensitivity of the questionnaire to change, for example, the tool's ability to detect clinically significant changes over time. Another limitation was patient selection. Only patients without cognitive deficits were covered in the research. Patients whose QoL had been affected by a recent seizure within three months, or other serious chronic, physical, or psychological illness, were also excluded from the study.

Disclosures and acknowledgements

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Artificial intelligence (AI) was not used in the creation of the manuscript.

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