



The Multiple Sclerosis Intimacy and Sexuality Questionnaire-15: Validity, reliability, and factor structure of Croatian version

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ABSTRACT

Introduction: Multiple sclerosis (MS) is a chronic progressive disease of the central nervous system that results in a wide range of clinical manifestations including sexual dysfunction (SD) and impaired sexual health. The aim of this study was to assess the validity, reliability, and factor structure of the MS Intimacy and Sexuality Questionnaire-15 (MSISQ-15) in Croatian-speaking patients.

Methods: Participants were 90 patients with MS participated in the study, including 50 women and 40 men (44 ± 13 years). The MSISQ-15 was utilized as the instrument, with its Croatian version developed using the forward-backward translation. Descriptive analysis was performed on the data. Reliability was assessed through Cronbach's α and test-retest analysis. Pearson's correlation was examining the relationship between the total scale and the SD subscales. Construct validity was evaluated with exploratory factor analysis.

Results: The mean for the total scale and its primary, secondary, and tertiary SD subscales were 33.39 ± 12.06 , 12.05 ± 5.36 , 11.22 ± 4.51 , and 10.12 ± 5.39 , respectively. The total scale demonstrated high internal consistency ($\alpha = 0.94$). Each SD subscale exhibited high internal consistency ($\alpha = 0.84-0.92$). The intra-class correlation for the SD subscales and the total scale was between 0.95 and 0.97. There was a strong relationship between the total scale and the SD subscales ($r = 0.76-0.93$). Bartlett's test of sphericity indicated a high and significant correlation ($\chi^2 = 939.94$, $p < 0.001$). The Kaiser-Meyer-Olkin measure is 0.87. The factors extracted accounted for 65.90% of the total variance, with factor loadings ranging from 0.61 to 0.84.

Conclusion: The Croatian MSISQ-15 version has demonstrated validity, reliability, and factor structure in assessing health-related quality of life in Croatian-speaking patients.

Keywords: Croatia; multiple sclerosis; reliability; sexual health; validity

INTRODUCTION

Multiple sclerosis (MS) is an inflammatory and demyelinating disorder leading to a diverse array of symptoms, including sexual dysfunction (SD) and impaired sexual health. Sexual health represents a specific domain of health-related quality of life (HRQoL) which includes physical, emotional, mental, and social well-being in relation to sexuality. Sexual health, or sexual activity and behavior, is significantly affected by MS in the majority of patients (1).

The prevalence of SD among women with MS ranges from 34% to 85% (2), while in men, it varies between 50% and 90% (3).

The MS Intimacy and Sexuality Questionnaire-19 (MSISQ-19) (4) was developed to address the issues in the sexual health domain of MS patients. A subsequent re-evaluation in a larger cohort led to the validation of a 15-item version (5). The MSISQ-19 is structured into three distinct SD subscales (SDS), primary, secondary, and tertiary which were initially defined by Foley et al. (6), confirmed by Weiss et al. (7) and further validated by Foley et al. (8). The original MSISQ-19 has been validated in several languages, Persian (9), Portuguese (10), Italian (11), French (12), and Greek (13). Primary SD inside MSISQ-19 questionnaire refers to neurological changes associated with MS that

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directly impacts sexual sensations and response (6,14,15). Secondary SD is related to MS-induced physical changes that indirectly affect sexual function, without directly involving the nervous pathways connected to the genital system (4). Tertiary SD involves the emotional, cultural, and social factors that influence sexual health (7,8,16-19).

The original validation of the MS Intimacy and Sexuality Questionnaire-15 (MSISQ-15) was carried out by Foley et al. (5). In the mentioned study, Foley et al. made re-validation of MSISQ-19 questionnaire. The four items were dropped from original 19-item version of the questionnaire. Mentioned items were excluded because they did not reach a criterion component loading of 0.60 or higher. All four excluded items were from the secondary SD subscale, so the final 15-item version of the questionnaire consisted of three five-item subscales (5). The MSISQ-15 has been successfully validated for use in Dutch (20), Italian (21), Greek (22), French (23), Polish (24), and Turkish (25) patients. This study aimed to assess the validity, reliability, and factor structure of the MSISQ-15 for Croatian-speaking individuals with MS.

METHODS

This prospective study analyzed data from 90 individuals with MS, comprising 50 women and 40 men, with a mean of 44 ± 13 years, all of whom were receiving neurological care at the Clinical Hospital Centre Osijek (Croatia). The mean score of patients' Expanded Disability Status Scale (EDSS) was 2.5 (EDSS range 0-8).

The research utilized the MSISQ-15 that includes primary, secondary, and tertiary SDS (4-5). Responses to the items in the MSISQ-15 are measured on a Likert scale ranging from 1 to 5. The total score ranges from 15 to 75, where higher scores indicate a greater impact of SD on the HRQoL. The scale does not distinguish between specific and non-specific SD, meaning that it serves as a general measure of SD. The interval between testing and retesting was 3 months. Permission for the validation of the original questionnaire into Croatian was obtained from the original developer (5). The translation process followed a forward-backward procedure. These translation and adaptation procedures are detailed in the works of Guillemain et al. (26) and Beaton et al. (27).

The sample size was calculated using G-Power with 0.5 effect size, a significance level of 0.05, and a statistical power of 0.80. Descriptive analysis was performed on the data. A Cronbach's α coefficient was computed for each SDS of the MSISQ-15 as well as for the total scale. A Cronbach's value >0.70 was considered indicative of excellent internal consistency (28). Test-retest reliability was evaluated to assess the reproducibility of the MSISQ-15. The similarity between the two separate assessments was measured with the intra-class correlation (ICC, 95% CI). An ICC value above 0.80 was regarded as demonstrating strong reliability (29). The normality of the distribution was tested with the Shapiro-Wilk test. To assess convergent validity, Pearson's correlation (r) was calculated to examine the relationship between the total scale and the SDS. A correlation coefficient >0.50 was interpreted as indicating strong validity, a value between 0.35 and 0.50 was considered moderate,

and a value less than 0.35 was viewed as weak validity (30). Construct validity was evaluated with exploratory factor analysis (EFA) with varimax rotation. The adequacy of the sample was considered sufficient with a Kaiser-Meyer-Olkin (KMO) value ranging from 0.70 to 1, while Bartlett's test of sphericity (BTS) confirmed statistical significance at $p < 0.001$, supporting the appropriateness of EFA for the data (31,32). The analysis included the examination of the scree plot, the proportion of variance explained by the factor model, and the patterns of factor loadings.

The data were collected over a period from September to October 2018 among MS patients who were receiving neurological care at the Clinical Hospital Centre Osijek (Croatia).

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethical approval for the study was granted by the Ethics Committee of the Clinical Hospital Centre Osijek (approval code: R2-4718/2018). Before participation, all patients provided written informed consent, and they were informed of their right to withdraw from the study at any time.

RESULTS

The mean scores (\pm standard deviation) for the total scale, as well as the primary, secondary, and tertiary SDS, were 33.39 ± 12.06 , 12.05 ± 5.36 , 11.22 ± 4.51 , and 10.12 ± 5.39 , respectively. The total scale demonstrated excellent internal consistency ($\alpha = 0.94$). The Cronbach's values for SDS were as follows: primary SDS 0.89, secondary SDS 0.84, and tertiary SDS 0.92 (Table 1).

The primary SDS exhibited a strong correlation with both the secondary SDS ($r = 0.62$) and tertiary ($r = 0.74$) SDS. A moderate correlation was observed between the secondary and tertiary SDS ($r = 0.47$). The total scale showed a strong correlation with the primary ($r = 0.93$), secondary ($r = 0.76$), and tertiary ($r = 0.85$) SDS (Table 2).

The test-retest reliability for all subscales and the total scale demonstrated excellent consistency. The intra-class correlation for the total scale and SDS ranged from 0.95 to 0.97 (Table 3).

The BTS for correlation matrix was highly significant ($\chi^2 = 939.94$, $p < 0.001$). The KMO of sampling adequacy was 0.87, suggesting that the correlation matrix among the variables was suitable for factor extraction. The calculated values fell within the acceptable range, confirming the adequacy of the sample size and study structure for conducting EFA. Based on the Guttman-Kaiser criterion, six factors with meaningful eigenvalues (7.71, 1.87, and 1.28) were identified. The factors, comprising 15 items across three dimensions, accounted for 65.90% of the total variance. The resulting factor loadings from the EFA are in Table 4.

DISCUSSION

The advancement of clinical practice and research relies on the adoption of valid and standardized measures, which would facilitate high-quality comparisons and meta-analyses of randomized controlled trials involving

TABLE 1. Descriptive statistics and internal consistency of MSISQ-15 total scale and sexual dysfunction subscales

Sexual dysfunction subscale	M \pm SD	Minimum score	Maximum score	Median (IQR)	Cronbach's α
Primary SDS	12.01 \pm 5.38	5	24	11 (9)	0.89
Secondary SDS	11.18 \pm 4.48	5	20	11 (8)	0.84
Tertiary SDS	10.04 \pm 5.37	5	25	8.5 (8)	0.92
MSISQ-15 total scale	33.23 \pm 13.09	15	64	31 (21)	0.93

MSISQ-15: Multiple Sclerosis Intimacy and Sexuality Questionnaire-15, SDS: sexual dysfunction subscale, M: mean, SD: standard deviation, IQR: interquartile range

TABLE 2. Intercorrelations between MSISQ-15 total scale and sexual dysfunction subscales

Sexual dysfunction subscale	Primary SDS	Secondary SDS	Tertiary SDS
Primary SDS	1		
Secondary SDS	r=0.60, <i>p</i> <0.001*	1	
Tertiary SDS	r=0.71, <i>p</i> <0.001*	r=0.49, <i>p</i> <0.001*	1
MSISQ-15 total scale	r=0.91, <i>p</i> <0.001*	r=0.79, <i>p</i> <0.001*	r=0.87, <i>p</i> <0.001*

MSISQ-15: Multiple Sclerosis Intimacy and Sexuality Questionnaire-15, SDS: sexual dysfunction subscale, r: Pearson's correlation coefficient, *: statistically significant correlation

TABLE 3. The test-retest reliability of the MSISQ-15 total scale and sexual dysfunction subscales

Sexual dysfunction subscale	Test M \pm SD	Retest M \pm SD	ICC (95% CI)
Primary SDS	12.01 \pm 5.38	12.50 \pm 5.07	0.974 (0.96-0.98)
Secondary SDS	11.18 \pm 4.48	11.56 \pm 4.05	0.951 (0.93-0.97)
Tertiary SDS	10.04 \pm 5.37	11.09 \pm 4.98	0.957 (0.93-0.97)
MSISQ-15 total scale	33.23 \pm 13.09	35.15 \pm 12.22	0.972 (0.95-0.98)

MSISQ-15: Multiple Sclerosis Intimacy and Sexuality Questionnaire-15, SDS: sexual dysfunction subscale, M: mean, SD: standard deviation, ICC: intra-class correlation coefficient, CI: confidence interval

individuals with this increasingly prevalent condition. To the best of our knowledge, this is the first study which conducted in Croatia to explore intimacy and SD issues in MS patients using the Croatian MSISQ-15 version.

This study confirmed the validation of the Croatian MSISQ-15 version and highlights its potential as an effective outcome measure in clinical trials. Our analysis demonstrated the construct validity and reliability of the Croatian MSISQ-15 version. The results regarding construct validity and reproducibility were consistent with those observed in international patient populations. These findings align with previous analyses of differential item functioning, which showed satisfactory results across various countries (5). Together with the initial validation findings (5), the present results underscore the significant strength of the MSISQ-15, particularly its concurrent validation process across multiple nations.

As previously noted, the original revalidation and development of the MSISQ-15 were conducted by Foley et al. (5). In their study, factor loadings ranged from 0.93 for the item "Apprehension about sexual rejection" to 0.61 for "Muscle stiffness or spasms in the arms, legs or body." The highest factor loading observed in their study was greater than the highest value we measured in our research. The mean total score in their study was 34.58, which is slightly higher than our result. In their findings, the highest mean was for the

TABLE 4. Exploratory factor analysis of the MSISQ-15

Variable	Factor loading
Factor 1: Tertiary SDS	
Feeling that my body is less attractive	0.84
Feeling less masculine or feminine due to MS	0.80
Fear of being rejected sexually because of MS	0.79
Worries about sexually satisfying my partner	0.68
Feeling less confident about my sexuality due to MS	0.66
Factor 2: Primary SDS	
Less feeling or numbness in my genitals	0.61
Lack of sexual interest or desire	0.79
Less intense or pleasurable orgasms or climaxes	0.75
Takes too long to orgasm or climax	0.67
Inadequate vaginal wetness or lubrication (woman)/ difficulty getting or keeping a satisfactory erection (men)	0.62
Factor 3: Secondary SDS	
Muscle tightness or spasms in my arms, legs, or body	0.80
Bladder or urinary symptoms	0.76
Bowel symptoms	0.66
Tremors or shaking in my hands or body	0.64
Pain, burning, or discomfort in my body	0.63

MSISQ-15: Multiple Sclerosis Intimacy and Sexuality Questionnaire-15, SDS: sexual dysfunction subscale, MS: multiple sclerosis

primary SDS, while the secondary SDS had the lowest. In our study, the highest mean was also for the primary SDS, but the lowest mean was for the tertiary SDS. Regarding internal consistency, Cronbach's value for the total score in their study was 0.92, with values of 0.87 for the primary SDS, 0.81 for the secondary SDS, and 0.90 for the tertiary SDS. In our study, internal consistency was slightly higher for the total score and for all SDS (5).

In 2020, Tzitzika et al. conducted the Greek version of the MSISQ-15 (22). The average total score for these patients was 30.64, with the scores for the SDS being 9.38 for the primary, 10.72 for the secondary, and 10.54 for the tertiary. The internal consistency of the total scale and the SDS was strong with Cronbach's values ranging from 0.71 for the secondary SDS to 0.84 for the tertiary SDS and the total scale, where $\alpha = 0.77$. The three SDS together accounted for 72.90% of the total variance. In contrast to our study, where all items were correctly loaded onto the predicted three factors, two items, "Bowel-related symptoms" and "Experiencing a diminished sense of masculinity or femininity" did not load as expected. Furthermore, one item that was predicted to load on the primary SDS "Diminished sensation or numbness in the genital region" was instead found to load on the secondary SDS factor (22).

In 2023, Lefebvre et al. conducted the French MSISQ-15 version (24). The mean scores for the total scale and primary, secondary, and tertiary SDS were 35.25, 12.57, 10.78, and

11.91, respectively. The Cronbach's value for the total scale was 0.90, while the primary, secondary, and tertiary SDS had values of 0.88, 0.74, and 0.90, respectively. In our study, the Cronbach's values were higher across all categories, indicating superior internal consistency. Regarding the correlations between the total scale and SDS, the tertiary SDS exhibited the strongest correlation with the total score ($r = 0.93$), followed by the primary SDS ($r = 0.91$). The secondary SDS showed the weakest correlation ($r = 0.30$). In comparison, our study showed a similar correlation for the primary SDS ($r = 0.93$), a higher correlation for the secondary SDS ($r = 0.76$) and a lower correlation for the tertiary SDS ($r = 0.85$). Concerning the standardized factor loadings, all items were strongly correlated with their respective SDS, except for one item "Involuntary tremors or shaking in the hands or body" which had a 0.34 (24).

The most recent study on the MSISQ-15, conducted by Dogan et al., focused on the validation of the Turkish version of questionnaire (25). The reported mean scores were as follows: total scale – 38.44, primary SDS – 13.81, secondary SDS – 12.21, and tertiary SDS – 12.42. The Cronbach's values ranged from 0.81 for the primary SDS to 0.94 for the total scale. These results were similar to those obtained in our study, with slightly lower SDS values and identical total scale reliability. In terms of correlations, the values in their study were higher than those in our research, demonstrating a strong agreement, with correlation coefficients from 0.98 to 0.99 (25).

Several limitations of the current study should be acknowledged:

1. One limitation is the sampling method employed, and we suggest that future studies utilize random sampling with larger sample sizes.
2. The sample size in this study was relatively small and not pre-determined. Nevertheless, our analysis, which demonstrated the validity and reproducibility of the MSISQ-15 in this smaller group, emphasizes the robustness of the instrument.
3. Additional research is necessary to examine the limitations and strengths of the MSISQ-15 in a prospective manner, involving a larger and more representative sample, especially with respect to different clinical subtypes of MS. Our team plans to conduct a prospective study, incorporating additional academic centers across Croatia, to assess the acceptability and compatibility of the Croatian version of the MSISQ-15 in clinical practice. This study will also include follow-up evaluations using the MSISQ-15 to assess its sensitivity to changes and its potential utility as a prognostic tool.

CONCLUSION

The findings indicate that the MSISQ-15 SDS exhibits a favorable pattern of correlations and internal consistency, aligning with the results from the original validation study of the MSISQ-15 questionnaire. Thus, the Croatian MSISQ-15 version is a reliable, valid, and feasible instrument for assessing and sexuality and intimacy in Croatian patients. It can be effectively utilized as an outcome measure in the treatment and care management of Croatian MS patients, mainly because of its validity, reliability, and factor

structure that were confirmed in this study.

DECLARATION OF INTERESTS

Authors declare no conflict of interest.

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