Cross-cultural adaptation and validation of the 12-item Multiple Sclerosis Walking Scale (MSWS-12) for the Brazilian population

Adaptação transcultural e validação da *12-item Multiple Sclerosis Walking Scale* (MSWS-12) para a população brasileira

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ABSTRACT

Gait impairment is reported by 85% of patients with multiple sclerosis (MS) as main complaint. In 2003, Hobart et al. developed a scale for walking known as The 12-item Multiple Sclerosis Walking Scale (MSWS-12), which combines the perspectives of patients with psychometric methods. **Objective:** This study aimed to cross-culturally adapt and validate the MSWS-12 for the Brazilian population with MS. **Methods:** This study included 116 individuals diagnosed with MS, in accordance with McDonald's criteria. The steps of the adaptation process included translation, back-translation, review by an expert committee and pretesting. A test and retest of MSWS-12/BR was made for validation, with comparison with another scale (MSIS-29/BR) and another test (T25FW). **Results:** The Brazilian version of MSWS-12/BR was shown to be similar to the original. The results indicate that MSWS-12/BR is a reliable and reproducible scale. **Conclusions:** MSWS-12/BR has been adapted and validated, and it is a reliable tool for the Brazilian population.

Key words: multiple sclerosis, gait, validation studies.

RESUMO

Distúrbios da marcha são relatados em 85% de pacientes com esclerose múltipla (EM), sendo uma de suas principais queixas. Hobart et al. desenvolveram uma escala de deambulação conhecida como *The 12-item Multiple Sclerosis Walking Scale (MSWS-12)* que associa as perspectivas dos pacientes com os métodos psicométricos. **Objetivo:** Realizar a adaptação transcultural e validar a MSWS-12 para a população brasileira com EM. **Método:** Participaram 116 indivíduos com EM definida segundo os critérios propostos por McDonald. As etapas do processo de adaptação transcultural foram tradução, retradução, revisão por um comitê de especialistas e pré-teste. Para validação, foi realizado teste e reteste da MSWS-12/BR, e comparação com MSIS-29 e T25FW. **Resultados:** Após a adaptação transcultural da MSWS-12/ BR, observamos que a versão brasileira está semelhante à original. Os resultados mostraram que a MSWS-12/BR é uma escala confiável e reprodutível. **Conclusões:** A MSWS-12/BR foi adaptada adequadamente e é válida e confiável para a população brasileira.

Palavras-Chave: esclerose múltipla, marcha, estudos de validação.

Multiple sclerosis (MS) is an autoimmune disease of the central nervous system that leads to progressive disability in young adults. A variety of neurological deficits such as motor weakness, spasticity, and ataxia may lead to significant walking gait impairment. The degree of this impairment is associated with severe dysfunction of various neurological systems such as alterations in muscle power, levels of spasticity, degree of instability due to impaired coordination and degree of sensory impairment. Gait impairment are reported as main complaint by 85% of MS patients, and more than one third of them do not retain the ability to walk 20 years after the diagnosis. Several studies have evaluated gait impairment in MS patients and reported that there is a phase with slower walking and shorter stride length, with prolonged double weight-bearing[1,2].

Gait assessment in MS is difficult, since most instruments currently used are not specific for MS or have not been adapted to the Brazilian population. Therefore, the reliability of such tests is undetermined. It is necessary to monitor the progress of patients and to seek scientific evidence based on the various types of therapeutic interventions. Thus, it is important to have gait assessment scales for MS[3-6].

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In order to obtain reliable measurements of disease progression, and to obtain a tool for assessing treatment efficacy with scientific credibility, it is necessary to consider certain psychometric properties using a valid and reliable method[7-10], which should be cross-culturally adapted.

Bearing this in mind, the authors conducted the cross-cultural adaptation to the Brazilian culture and validation of the scale developed by Hobart et al, in 2003[11], a walking scale known as The 12-item Multiple Sclerosis Walking Scale (MSWS-12), specific for MS patients.

METHODS

The present study was approved by the Ethics Committee of Irmandade Santa Casa de Misericórdia de São Paulo (ISCMSP), Protocol nº 227/11. One hundred and sixteen subjects were randomly selected among patients with MS defined in accordance with the criteria proposed by McDonald, from the MS Care and Treatment Center (*Centro de Atendimento e Tratamento da Esclerose Múltipla*, CATEM). The patients were informed about the study signed and informed consent form before participating in it.

The sample comprised individuals with confirmed MS diagnosis, according to McDonald's criteria, who were able to walk, even using auxiliary devices. There was no restriction as to the stage of disease development in order for patients to be included in the study.

The exclusion criteria were: presence of other neurological diseases, and patients having experienced a relapse 30 days prior to the assessment.

In the first stage, the MSWS-12 was culturally adapted to the Portuguese language, in accordance with the proposals of Beaton et al.[10]. In summary, the scale was firstly translated into Portuguese by two bilingual Brazilians with knowledge about health terminology. The next step was to evaluate the translation to ensure semantic equivalence and acceptability. Subsequently, the Portuguese version was back-translated into English and compared with the original one. After pilot testing, the translated questionnaire was applied to a sample of ten MS patients at CATEM. The final stage of the adaptation process was a submission of all the reports and forms to the committee keeping track of the translated version.

In the second stage, 116 patients with diagnosis of MS at CATEM were assessed using the final version in Portuguese: MSWS-12/BR (test). Fifteen days later, the same author re-tested 56 patients, in order to observe the validity and reliability of the MSWS-12/BR.

Two types of reliability parameters were considered: internal consistency and scale test-retest reproducibility. The convergent and discriminant construct validity of the MSWS-12/BR were determined by examining correlations with the Portuguese version of the following scales: Multiple Sclerosis Impact Scale (MSIS-29/BR), Timed 25-foot Walk (T25FW) and Expanded Disability Status Scale (EDSS).

The MSWS-12/BR is a scale that assesses patient-rated measurement of his/her walking quality. Each item is scored on a scale from one to five. A total score is generated and reported on a scale from zero to 100. The final result for the total score is obtained by subtracting the minimum possible score (12) from the patient's total score, and then dividing the result by the maximum possible score (60) and multiplying the result by 100. Higher scores indicate greater impact of walking gait disability on the quality of life of patients with MS[11-13].

The Expanded Disability Status Scale (EDSS) is an observer-rated (the neurologist) scale which grades disability due to MS in 20 steps on a continuum from 0 (normal neurological examination) to 10 (death due to MS)[14-16].

The MSIS-29/BR is a MS patient-rated measurement of quality of life. It consists of 29 questions, among which 20 address the physical impact component, and nine assess the psychological impact. A score is thus generated and reported on a scale from 0 to 100, on which lower scores indicate better quality of life[16-18].

The Timed 25-foot Walk (T25FW) was carried out on an area painted with a white strip, measuring 7.62 meters (25 feet), in a corridor at CATEM with an anti-slip floor surface. The patient was instructed to wear comfortable shoes, and to use an assistive device if necessary. A timer (stopwatch) was required to measure the time needed to cover the 25-foot distance in seconds[19,20]. The subject was instructed to walk from the starting point as safely and as quickly as possible. Two consecutive attempts were made, with a rest period in between. The final result was the mean value.

Statistical analysis

The significance level was set at 5% (0.05). The variables were processed in a database and the statistical analysis was carried out using the SPSS 13.0 software. To test reliability, the internal consistency of the MSWS-12/BR was assessed using Cronbach's alpha and Pearson's correlation coefficient calculations. The inter-rater reliability was assessed using the intraclass correlation coefficient (ICC). Finally, the validity of the instrument was assessed by analyzing the correlations of the MSWS-12/BR with EDSS, T25FW and MSIS-29/BR. In addition, the results were compared with other sociodemographic variables using Student's t test and Pearson's correlation coefficient.

RESULTS

Cross-cultural adaptation of the MSWS-12 instrument to the Portuguese language

After the processes of translation and back-translation of the Multiple Sclerosis Walking Scale, an evaluation and comparison

of two Portuguese versions of the scale was carried out by five individuals forming an Expert Committee (two physiotherapists, a medical doctor, an engineer and an English teacher).

After the review, and having two translations of the original scale, a consensus on any discrepancy was reached and equivalence was obtained in four areas: semantic, idiomatic, experiential and conceptual. The version of the language translation of the MSWS-12 named "1" was considered to be the final version of the Portuguese MSWS-12/BR.

Ten patients who had been randomly selected to perform the pretest had no difficulty in understanding the 12 items of the MSWS-12/BR.

Clinical application of the MSWS-12/BR and evaluation of measurement properties

The demographic data of the participants are shown in Table 1. The analyses on the T25FW, the physical and psychological components of the MSIS-29/BR and the test and retest of the MSWS-12/BR are presented in Table 2.

The reliability could be seen through the scale test-retest reproducibility and internal consistency. The reproducibility obtained from the ICC (95%CI) for the MSWS-12/BR was 0.865 (0.78–0.92). The internal consistency from Cronbach's alpha test was 0.943 and 0.951 for test and retest of MSWS-12/BR, respectively.

Table 1. Sociodemographic characteristics of the studied population.

		Frequency	%
Age (years)	Mean (SD)	38.26 (±10.31)	
	Minimum/ Maximum	17/65	
Gender	Female	94	81
	Male	22	19
		116	100
Education	Elementary	7	6
	High school	56	48.3
	Higher education	53	43.7
		116	100
Marital status	Married	55	47.4
	Single	51	44
	Widowed	8	6.9
	Separated	2	1.7
		116	100
Type of disease	Relapsing remitting	109	94
	Primary progressive	5	4.3
	Secondary progressive	2	1.7
		116	100
EDSS	Mean (SD)	2.67 (±1.94)	
	Minimum/ Maximum	0/7	
Assistive device	Without device	82	70.7
	Cane	31	26.7
	Crutch	3	2.6
		116	100

EDSS: Expanded Disability Status Scale; SD: standard deviation.

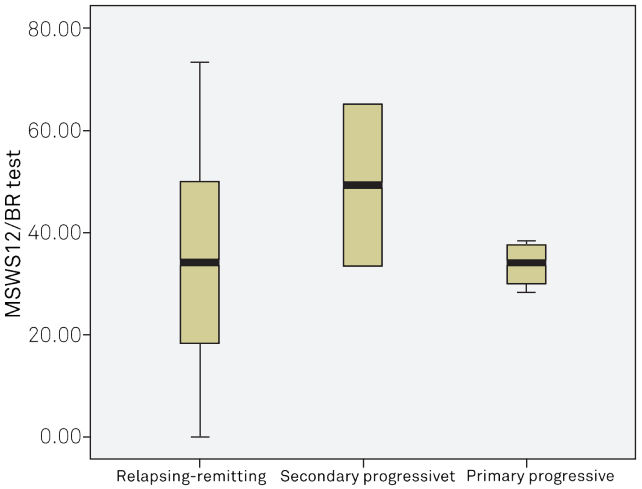
To analyze the internal consistency of the items in the test, Cronbach's alpha was performed with MSWS-12/BR data, taking into consideration each item in the test (0.935–0.945) and retest (0.942–0.951). It could be seen that no item interfered negatively with the MSWS-12/BR instrument, i.e. all the items on the scale were stable.

The comparison between test and retest of MSWS-12/BR and the sociodemographic variables are shown in Table 3. Student's t test was used for variables such as gender, education, marital status and assistive device.

To compare marital status in the test and retest of the MSWS-12/BR, only single and married statuses were taken into consideration, since there was a small number of widow or divorced patients. Likewise, as to schooling, the elementary education level was represented by seven patients in the test and four patients in the retest. Therefore, Student's t test was used for the variables of high school education and university education only. As to assistive devices, patients were divided into a group requiring an assistive device and another not requiring it.

In the descriptive analysis on the correlation between the types of disease presented by the patients tested using the MSWS-12/BR, the results shown in the box plot (Fig 1) suggested that patients presenting relapsing-remitting (RR) MS could walk more satisfactorily than patients with other forms of the disease. The other forms, namely primary progressive (PP) and secondary progressive (SP) MS, were found to have similar characteristic features in the test and retest.

The Pearson's correlation values for variables such as age and EDSS, and the results from the T25FW and MSIS-29/BR relating to physical and psychological aspects of the disability, as assessed by the test and retest using the MSWS-12/BR, are shown in Table 4. Fig 2 and 3 show strong correlations between the MSWS-12/BR and the T25FW and physical aspects of the MSIS-29/BR, which showed similar features in the test and in the retest.



MSWS-12/BR: Portuguese version of the 12-item Multiple Sclerosis Walking Scale.

Fig 1. Boxplot for MSWS-12/BR test as to the type of disease.

Table 2. Comparative analysis of the physical and psychological aspects of the MSIS-29/BR, the T25FW, and the test and retest of the MSWS-12/BR.

		n	Mean	Standard Deviation	Minimum	Maximum
T25FW (seconds)		90	8.5	2.8	3.1	17.9
MSIS-29/BR	Physical	91	34.3	25.6	0	93.8
	Psychological	91	37.5	27.7	0	100
MSWS-12/BR	Test	116	33.09	18.52	0	73.3
	Retest	56	33.00	19.86	0	73.3

MSIS-29/BR: Portuguese version of Multiple Sclerosis Impact Scale; T25FW: Timed 25-foot Walk; MSWS-12/BR: Portuguese version of the 12-item Multiple Sclerosis Walking Scale.

Table 3. Comparison between the test and retest of MSWS-12/BR as to gender, education, marital status, type of disease and use of assistive device.

			n	Mean	Standard deviation	Minimum	Maximum	p-value
Gender	Test	Male	22	27	16.6	0	56.7	0.415
		Female	94	31	21.2	0	73.3	
	Retest	Male	16	32.3	18.5	0	58.3	0.415
		Female	40	33.3	20.6	0	73.3	
Education	Test	Elementary	7	37.4	8.38	28.3	55	
		High school	56	28	20.7	0	68.3	0.359
		Higher education	53	31.6	21.1	0	73.3	
	Retest	Elementary	4	41.7	14.6	25	58.3	
		High school	27	32.3	20.8	0	66.7	0.888
		High education	20	31.5	20.1	0	73.3	
Marital status	Test	Single	51	30.3	20.2	0	73.3	0.749
		Married	55	29	21.2	0	70	
		Separated	8	36.3	16.2	0	51.7	
		Widowed	2	36.7	28.3	16.7	56.7	
	Retest	Single	27	38.1	18.3	3.3	73.3	0.065
		Married	24	27.8	21	0	58.3	
		Separated	5	30.3	19.3	0	48.3	
		Widowed	-	-	-	-	-	
Type of disease	Test	RR	109	32.4	19.03	0	73.3	
		SP	2	49.2	22.39	33.3	65.0	
		PP	4	33.8	4.6	28.3	38.33	
	Retest	RR	82	31.8	20.6	0	73.3	
		SP	31	46.7	2.4	45	48.3	
		PP	3	41.7	8.1	30	48.3	
Assistive device	Test	Without device	82	22.7	17.9	0	68.3	<0.001*
		Cane	31	43.1	13.8	23.3	73.3	
		Crutch	3	38.9	8.6	31.7	48.3	
	Retest	Without device	33	23.6	19.3	0	66.7	<0.001*
		Cane	21	47.1	11	25	73.3	
		Crutch	2	39.2	13	30	48.3	

RR: relapsing remitting; SP: secondary progressive; PP: primary progressive; MSWS-12/BR: Portuguese version of the 12-item Multiple Sclerosis Walking Scale; *p-value less than 0.05.

Table 4. Pearson's correlation comparing the test and retest of the MSWS-12/BR as to age, EDSS, T25FW and MSIS-29/BR physical and psychological aspects.

MSWS-12/BR		Age	EDSS	T25FW	MSIS-29/BR Physical	MSIS-29/BR psychological
Test	Pearson's correlation	0.247	0.478	0.577	0.803	0.495
	p-value	0.008	0.000*	0.000*	0.000*	0.000*
	n	116	78	90	91	91
Retest	Pearson's correlation	0.186	0.426	0.604	0.757	0.519
	p-value	0.170	0.003	0.000*	0.000*	0.000*
	n	56	45	48	51	51

EDSS: Expanded Disability Status Scale; MSIS-29/BR: Portuguese version of Multiple Sclerosis Impact Scale; T25FW: Timed 25-foot Walk. *significance with p value less than 0.05.

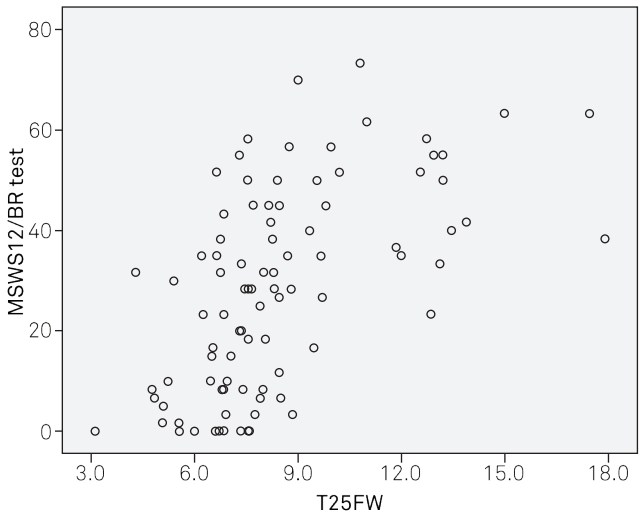


Fig 2. Dispersion diagram between MSWS-12/BR test and T25FW.

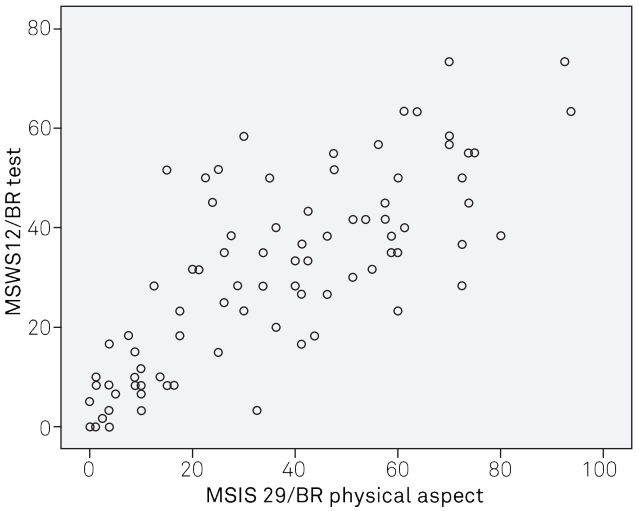


Fig 3. Dispersion diagram between MSWS-12/BR test and MSIS-29/BR physical aspect.

DISCUSSION

Neurological deficits such as motor weakness, spasticity, ataxia and sensory disturbance are common even at early stages of MS and may lead to significant gait impairment. The degree of impairment is associated with the severity of dysfunction in various neurological systems[1]. Gait disorders are reported as main complaint by 85% of MS patients, and over one third of them do not retain the ability to walk 20 years after the diagnosis. Impaired walking can be a marker of both disability and disease progression and, therefore, it is an important outcome measurement when it comes to treatment and rehabilitation of diseases such as MS[1,21-23]. The relevance of our study lies in its quantification of patients' perception of the impact of MS on walking ability. In this study, we found that the impact of MS on walking ability was 50.16% in the test and 53% in the retest.

Rigorous measurements of this ability are needed for clinical trials and clinical practice, to ensure that the results are reliable and valid. In MS, a number of generic and disease-specific walking measurements have been used. These include the T25FW and the Ambulation Index. Other measurements of physical functions are biased toward walking. For example, the EDSS assesses walking ability in the range of 3.5 to 7.5. The ten-item physical functioning dimension of the Medical Outcomes Study 36-Item Short Form Health Survey (SF-36) has six items evaluating walking. The seven-item mobility scale of the Functional determination of quality of life in MS (FDQL) has one item assessing the ability to walk. Guy's Neurological Disability Scale (GNDS) has one item that addresses lower-limb disability. Only three of the mentioned scales (SF-36, FDQL and GNDS) incorporate the patients' self-evaluation[11].

All these scales have limitations as to the measurement of walking ability. Some of these limitations relate to specific issues. For example, although the T25FW may be simple, it assesses only the ability to walk a given distance, the stride length and the walking speed. The EDSS and the walking items of the SF-36 focus on walking distances, whereas the lower-limb disability item of the GNDS focuses on the use of walking aids. The walking item of the FDQL mobility scale asks the patient about the extent of trouble in walking. The EDSS and SF-36 have limited MS measurement properties[11,24].

Hobart et al. developed a patient-based measurement on an important clinical problem of the disease with considerable public health impact. Twelve items were generated from patient interviews, experts' opinion and literature review. The results from a two-stage evaluation provided evidence that the MSWS-12 was acceptable, reliable, valid and responsive. In addition, the self-reported MSWS-12 might offer measurements of greater flexibility and simplicity in clinical practice and clinical trials than do observer-rated scales. It has the potential to be used in cross-sectional studies evaluating the impact of MS on walking, in longitudinal studies to monitor changes in walking over time and, most importantly, in clinical trials to evaluate the therapeutic effectiveness from the patients' perspective. The purpose of the present study was to achieve cross-cultural adaptation and validation of this tool in order to use it among the Brazilian population with MS.

The steps of the cross-cultural adaptation process proposed by Beaton et al in 2002[10] were followed in the present study, in which there was a sequence of translation, back-translation, expert committee review and pretesting.

Following the cross-cultural adaptation of the MSWS-12/BR, it was observed that our so-called version 1 was equivalent to the semantic, idiomatic, experiential and conceptual aspects of the original document. We agree with Ciconelli et al.[25], who reported that each society has its own beliefs, attitudes, customs, behavior and social habits, and that these features give people guidance on who they are, how they should behave and what they should not do. These rules or concepts reflect the culture of a country and distinguish populations.

Evaluation of measurement properties is also a critical step in the process of cross-cultural adaptation, when seeking compatibility between the MSWS-12/BR and the original document regarding reliability and validity.

The second instrument review criteria (SAC)[26], i.e. the values of Cronbach's alpha coefficients, can vary from 0 to 1, and values greater than 0.7 are associated with good reliability. In the present study, Cronbach's alpha coefficient was 0.94 and 0.95 for the test and retest, respectively. These results are similar to those reported by Hobart et al.[11] and McGuigan and Hutchinson[12], in which Cronbach's alpha coefficient was 0.97 for both studies. These values confirm that Cronbach's alpha coefficient presented good reliability, i.e. there was a high degree of consistency and accuracy for this tool when used for evaluating the impact of MS in walking ability.

Analyses on deletion of items from the scale showed high internal consistency, which means that all the items of the MSWS-12/BR were stable. Therefore, individual items of the instrument scale cannot affect the result negatively.

The reproducibility of the MSWS-12/BR through the 95%CI was similar to what was found by the creators of the scale. In the present study, CI was 0.865 (0.78–0.92), while in the study by Hobart et al.[11], it was 0.94 (0.75–0.82). As previously mentioned, CI values closer to one indicate better reproducibility of the scale.

The construct validity of a scale assesses the degree to which the instrument can measure a concept with scientific purposes. The convergent validity of a scale evaluates the extent to which two or more instruments that assess the same attribute agree with each other[7-10]. In the present study, the MSWS-12/BR was compared with the physical aspect of MSIS-29/BR, T25FW and EDSS. It was observed that all the scales and tests measured the walking disability of patients with MS, using Pearson's correlation test (Table 4).

Our results were similar to those found by Hobart et al in 2003[11] with regard to the correlation between the MSWS-12/BR and the physical aspect of MSIS-29/BR (r=0.803 for the test and 0.757 for the retest). These values emphasize the strong correlation that existed between walking ability and physical function. However, one cannot replace the other.

The substantial correlations found for the MSWS-12/BR with the T25FW (r=0.58 for the test and 0.60 for the retest) suggest that the time taken to walk a given distance is a limiting indicator of the patients' perceptions of their walking limitations. This is because the T25FW is a specific test used to evaluating walking ability, while the MSWS-12/BR is a self-reported scale assessing the patients' perception of the impact of MS on their walking ability.

The correlation between the EDSS and the MSWS-12/BR test and retest was positive. This result was confirmed by the Pearson's correlations of 0.48 and 0.43, respectively, i.e. the higher the disability (EDSS) was, the greater the impact on walking was. The same result was observed by Motl and Snook[13], thus confirming the validity of the scale.

Another important point to bear in mind is the extent to which other symptoms such as mood and emotional disturbances influence self-ratings of walking impairment. The correlation between the MSWS-12/BR and the MSIS-29/BR psychological scale was 0.45, with a significant p-value, thus showing that there was a substantially positive correlation between these parameters. The same result was found by Hobart et al.[11], in which a correlation of 0.32 was shown.

The results from the present study showed significant differences relating to gender, education or marital status between the test and retest of the MSWS-12/BR, as shown in Table 3. These variables did not change the scores of the MSWS-12/BR, i.e. they did not have any impact on walking dysfunction.

Gait impairment is common in MS cases, and difficulties in walking have been reported in 78.8% of the patients with chronic progressive MS and in 20.1% with RR MS. Even though walking difficulties are more prevalent in the chronic phase of the disease, subtle changes in gait parameters may be detectable even in the early stages of MS. In general, walking impairment has a negative impact on personal activities, and this is not only restricted to motor domains (for example, incontinence due to inability to reach a toilet in time) and participation (access to locations), but also associated with loss of physical quality of life[27]. This may explain the relationship between the type of disease and the MSWS-12/BR, given that because most of the subjects were RR (94%), they showed values lower than those of subjects with PP (4,3%) and SP (1,7%). In other words, RR MS subjects experienced less impact on walking than did those with progressive forms of the disease.

The present results are in agreement with Albrecht et al.[3], who reported that the ability to walk and the ability to walk without an assistive device are essential factors in the quality of life of patients with MS. The present study showed a relationship between the MSWS-12/BR and the use of an assistive device, meaning that subjects requiring it to walk had higher scores than subjects without this need. This result was statistically significant, with p-values of <0.001 and 0.002, respectively, thus showing that use of an assistive device had a great impact on walking.

These data are important, since many patients with MS rely on assistive devices. It has been reported that the use of cane among individuals with MS is twice as frequent as among patients aged 18–64 with any other neurological disease[22,28]. In the present study, 29.3% of the subjects used a type of assistive device.

Validation of an assessment instrument for a given population is necessary and should follow rigorous statistical analyses to evaluate its psychometric properties[7-10]. The present results provide knowledge about the characteristics of the MSWS-12/BR.

In conclusion, the MSWS-12/BR has been adapted for Brazilian patients with MS, and is equivalent to the original version (MSWS-12) as to the semantic, cultural and idiomatic characteristics.

The MSWS-12/BR is a valid, reliable and reproducible scale that can be used among Brazilian patients with MS.

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