DOI: 10.590/1809-2950/12654921042014

SYSTEMATIC REVIEW

Assessment of fatigue in multiple sclerosis: methodological quality of adapted original versions available in Brazil of self-report instruments

Avaliação da fadiga na esclerose múltipla: qualidade metodológica das versões originais adaptadas no Brasil dos instrumentos de autorrelato

Evaluación de fatiga en la esclerosis múltiple: cualidad metodológica de las versiones originales ajustadas en Brasil de los instrumentos de autoinforme

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ABSTRACT | Assessment of fatigue in multiple sclerosis is a difficult task and its instruments have no uniformity regarding the methodological evaluation parameters to ensure validity and reliability of its inferences. The objective of this study was to analyze the methodological quality of development, cross-cultural adaptation to Portuguese language (Brazil), and psychometric properties of self-report instruments that assess fatigue in multiple sclerosis and are available in Brazil. A search was conducted in the electronic databases LILACS, MEDLINE, Embase, PsycINFO, CINAHL, SciELO and SPORTDiscus with analysis of the selected instruments by consensus-based standards for the selection of health measurement instruments. It was included 10 articles and presented the instruments Fatigue Severity Scale (FSS), Modified Fatigue Impact Scale (MFIS), Cognitive and Physical Fatigue in Multiple Sclerosis Scale (CPF-MS), Guy's Neurological Disability Scale (GNDS), Functional Assessment of Multiple Sclerosis (FAMS), and their adapted versions in Brazil. Most instruments present a multidimensional structure with documented cross-cultural adaptation in Brazil and emphasize the physical domain and adequate reliability. There is difficulty in identifying a self-report instrument to adequately assess fatigue in multiple sclerosis and that is an example of methodological and psychometric standards in their design and management.

Keywords | Fatigue; Multiple Sclerosis; Psychometrics; Self Report.

RESUMO | A avaliação da fadiga na esclerose múltipla é uma tarefa difícil e seus instrumentos não dispõem de uniformidade quanto aos parâmetros de avaliação metodológica para assegurar validade e confiabilidade de suas inferências. O objetivo deste estudo foi analisar a qualidade metodológica do desenvolvimento, da adaptação transcultural para a língua portuguesa (Brasil) e das propriedades psicométricas dos instrumentos de autorrelato que avaliam a fadiga na esclerose múltipla e estão disponíveis no Brasil. Foi realizada uma busca eletrônica nas bases de dados LILACS, MEDLINE, Embase, PsycINFO, CINAHL, SciELO e SPORTDiscus, com análise dos instrumentos selecionados pelo consenso de parâmetros para selecionar instrumentos na área da saúde. Foram incluídos dez artigos e apresentados os instrumentos *Fatigue Severity Scale* (FSS), *Modified Fatigue Impact Scale* (MFIS), escala de fadiga cognitiva e física na esclerose múltipla (CPF-MS), escala de incapacidade neurológica de Guy (GNDS), *Functional Assessment of Multiple Sclerosis* (FAMS) e suas respectivas versões adaptadas no Brasil. A maioria dos instrumentos é multidimensional, específica, com documentada adaptação transcultural e predomínio de avaliação do domínio físico da fadiga e evidência de confiabilidade adequada. Houve dificuldade em se identificar um instrumento de autorrelato, que avalie adequadamente a fadiga na esclerose múltipla e seja exemplo de padrões metodológicos e psicométricos em sua concepção e administração.

Descritores | Fadiga; Esclerose Múltipla; Psicometria, Autorrelato.

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Presentantion: Dec. 2013 – Accepted for publication: Sep. 2014 – Financing source: none – Conflict of interests: nothing to declare.

RESUMEN | La evaluación de fatiga en la esclerosis múltiple es una tarea difícil y sus instrumentos no disponen de uniformidad cuanto a los parámetros de evaluación metodológica para garantir la validad y confiabilidad de sus inferencias. El objetivo de eso estudio fue analizar la cualidad metodológica del desarrollo, de la adaptación transcultural para el idioma portugués (Brasil) y de las propiedades psicométricas de los instrumentos de autoinforme que evalúan la fatiga en la esclerosis múltiple y están disponibles en Brasil. Se realizó una búsqueda electrónica en las bases de datos LILACS, MEDLINE, Embase, PsycINFO, CINAHL, SciELO e SPORTDiscus, con un análisis de los instrumentos seleccionados por el consenso de parámetros para seleccionar instrumentos en el área de la salud. Fueron inclusos diez artículos y presentados la *Fatigue Severity Scale* (FSS), la *Modified Fatigue Impact Scale* (MFIS), la escala de fatiga cognitiva y física en la esclerosis múltiple (CPF-MS), la escala de incapacidad neurológica de Guy (GNDS), la *Functional Assessment of Multiple Sclerosis* (FAMS) y sus respectivas versiones ajustadas en Brasil. La mayoría de los instrumentos es multidimensional, específica, con documentada adaptación transcultural y predominio de la evaluación del dominio físico de la fatiga y evidencia de la confiabilidad adecuada. Hubo dificultad en identificarse un instrumento de autoinforme, que haga una evaluación adecuada de la fatiga en la esclerosis múltiple y sea ejemplo de los estándares metodológicos y psicométricos en su concepción y administración.

Palabras clave | Fatiga; Esclerosis Múltiple; Psicometría; Autoinforme.

INTRODUCTION

Fatigue is the most incapacitating and common symptom of multiple sclerosis (MS)[1,2]. Studies show that 75 to 96% of people with MS have such condition[3]. In Brazil, fatigue in MS is estimated between 66.7 to 86.7%[4]. The frequency and impact of this symptom emphasize the importance of its assessment and diagnosis[5].

The assessment of fatigue in MS is a difficult task. The lack of a definition and consensus on its dimensions constitute the greater challenge at hand[5,6]. The MS Board for Guidelines on Clinical Practice[7] defines fatigue as a subjective lack of physical or mental energy perceived by the individual or by the caretaker and which interferes in daily life activities. The British society, on the other hand, defines it as a great sensation of tiredness without any apparent reason[1].

The fatigue in MS has a multidimensional nature due to a complex multifactorial interaction[2,8]. Kos et al.[9] related it to primary mechanisms related to the inflammatory process, to the disfunção do eixo neuroimunoendócrino, to alteration on the cerebral cortex activation and to secondary mechanisms such as sleep, activity reduction, depression, anxiety, psychological alterations, pain and use of medication.

Over the last 20 years, approximately 30 self-report instruments assessing fatigue in MS have been developed[2]. In Brazil, only five of those are available[4,10-12]. The assessment of fatigue in Brazilian individuals who have MS is made through the use of self-report instruments: The fatigue severity scale (FSS)[4], the modified fatigue impact in MS scale (MFIS)[11], the cognitive and physical fatigue in multiple sclerosis scale (CPF-MS)[12], the Guy's neurological disability scale (GNDS)[10] and the functional assessment of multiple sclerosis (FAMS)[13].

The wide scope of fatigue in MS may justify the existence of a great number of instruments intending to assess it, contemplating objective and subjective parameters with uni or multidimensional focus between specific or generic types[2,8,14-17]. However, according to evidence, the subjective methods, specially self-report instruments, are best suited in order to assess the fatigue[17].

The validity of the inferences of the studies depend directly on the quality of the measurement instruments[18]. Thus, the adoption of parameters and the analysis of psychometric properties in the development and validation of an instrument is essential, in order to ensure it really assesses that which is proposed and demonstrate reliability[10,19,20].

The Brazilian studies which adapted the self-report instruments assessing fatigue in MS are not uniform as for their parameters for the analysis of methodological quality, ensuring the reliability of its inferences. Thus, this study aims at analyzing the methodological quality of the development, the transcultural adaptation into the Portuguese language (Brazil) and the psychometric properties of the self-report instrument assessing the fatigue in MS available in Brazil.

METHODOLOGY

An electronic search was conducted in the virtual data bases of LILACS (1986-2013), MEDLINE (1966-2013), Embase (1974-2013), PsycINFO (1806-2013), Cinahl (1981-2013), SciELO (1998-2013) and SPORTDiscus (1985-2013), using the keywords "*esclerose múltipla*", "*fadiga*", "*adaptação transcultural*", "*psicometria*" and their respective terms in English cross-crossing them with the Boolean operator "and". Studies presenting the development

of original versions of the self-report instruments were included here, in order to assess the fatigue in MS available in Brazil, and the transcultural adaptation studies and psychometric analysis of the Brazilian versions. We excluded editorials, letters, guidelines and reviews.

In the search, 51 studies were found and 10 of them were selected. Out of the 41 excluded ones, 32 investigations presented transcultural adaptations to other languages different from the original one in which the instrument was developed, six studies presented review design and three of them investigated, at the same time, the fatigue in individuals with MS or Parkinson disease or stroke and presented the data all together.

Among the tem selected ones for this review, five of them approached the development and psychometric analysis of the original self-report instruments which assess the fatigue in MS and five of them are about the adaptation processes and the psychometric analysis of their Brazilian versions. The original versions of the instruments are Fatigue Severity Scale (FSS)[15], Modified Fatigue Impact Scale (MFIS)[19], CPF-MS)[20], GNDS[21], Functional Assessment of Multiple Sclerosis (FAMS)[22] and their respective adapted Brazilian versions, ESF/BR[4], MFIS/BR[11], CPF-MS/BR[12], GNDS/BR[10] and DEFU[13].

Two independent authors performed the analysis of methodological quality of the articles according to the Consensus-based Standards for the selection of health Measurement Instruments (COSMIN)[23], which is based on the protocol of Beaton et al.[24], and the Instrument Review Criteria (1995)[25]. The texts were analyzed as for the way their instruments were developed, to the description of transcultural adaptation of the Brazilian versions and to the analysis of psychometric properties. In order to assess the development of the instruments, we considered they have been pre-tested in individuals with MS in an open interview system, in which the interviewee may suggest changes and comment how he feels concerning the item asked[25].

The transcultural adaptation analysis of the instruments was based on the steps proposed by Beaton et al.[24]: translation into the language in which it will be used, consensual analysis of the translation, back translation to the original language of the instrument, consensual analysis of the back translation, review by a committee of specialists in the assesses phenomenon and testing of the pre-final version in individuals who have the condition. In the psychometric analysis, we considered as acceptable what is recommended by the Instrument Review Criteria (1995)[25]: reliability ($0.70 \leq$internal consistency≤ 0.90, reproducibility>0.80), validity (correlation coefficient>0.75), sensitivity (determining the cut-off point of the instrument), responsiveness (effect size assessment), quality of the data (proportion higher than 15% of the respondents who reach the highest score (ceiling effect) or lower instrument score (floor effect)). In relation to practicality, the time and easiness of administration of the instrument were analyzed. As for its representativeness, it is recommended the selection of between 5 and 10 individuals per item of the instrument being assessed[26]. The adjustment to the item response theory (IRT) refers to the absence of biases between the items[27].

RESULTS

The main characteristics of the studies included are in Table 1. Although the instruments present a wide range of fatigue dimensions, the physical domain prevailed. There was limitation in the development of versions CPF-MS, CPF-MS/BR, ESF and ESF/BR, since they were not pre-tested in individuals with MS. The instruments DEFU and GNDS and their versions in Portuguese were introduced as indirect assessment of fatigue, because they present domains related to this symptom.

The representativeness of the sample was acceptable only for versions DEFU, GNDS/BR and MFIS. On the other hand, FSS and MFIS are generic instruments, however the ESF/BR and MFIS/BR were adapted for individuals with MS.

There is scarce information on the psychometric properties of the instruments (Table 2). No study demonstrated an assessment of all the proposed psychometric properties. The reliability was the most assessed property and the one with the most adequate values. There is no information on the sensitivity level of the instruments and the quality of the data, though there is the determination of the cut-off point.

DISCUSSION

This study is the first one to analyze the evidences as for the psychometric properties of the self-report instruments which assess the fatigue in Brazilian individuals with MS.

Most analyzed instruments recommend the multidimensional fatigue assessment in agreement to the literature. Considering the multifactorial interaction of the Genesis of the fatigue in MS, there is a need of a combination of dimensions in order to assess this symptom,

Table 1. Characteristics of the included studies

Instrument of the sample	Construction	Population	Domains (items)	Score (cut-off point)	Brazilian version (transcultural adaptation) of the sample
FSS[15] MS: 25/ LES: 29/ Controls: 20	Severity of the fatigue	MS LES	Physical (9)	1-7 (≥28)	ESF/BR[4] (No) MS:15/ Controls:15
MFIS[19] MS:151	Impact of the fatigue	Chronic diseases	Physical (9) Cognitive (10) Social (2)	0-4 (≥38)	MFIS/BR[11] (Yes) MS: 57/ Controls: 45
CPF-MS[20] MS: 39/ Controls: 19	Physical and cognitive fatigue	MS	Physical (8) Cognitive (7)	1-5 (No)	CPF-MS/BR[12] (Yes) MS: 34/ Controls: 24
FAMS[22] EM: 433	Quality of life	MS	Mobility (7) Symptoms (7) Emotional state (7) Personal satisfaction (7) Thought/fatigue (9) Social situation/family (7)	0-4 (No)	FAMS[13] (Yes) MS: 143
GNDS[21] MS: 50	Function	MS	Cognitive, humor, sight, speech, deglution, function of the UL, function of the LL, vesicle control, intestines control, sexual function, fatigue and others (1 each)	0-5 (No)	GNDS/BR[10] (Yes) MS: 62

FSS: Fatigue Severity Scale; MS: mutilpe sclerosis; LES: lúpus eritematoso sistêmico; ESF/BR: Fatigue Severity Scale (Brazilian version); MFIS: Modified Fatigue Impact Scale; MFIS-BR: Modified Fatigue Impact Scale (Brazilian version); CPF-MS: functional assessment of multiple sclerosis; CPF-MS/BR Brazilian version; FAMS: Functional Assessment Multiple Sclerosis; DEFU: functional assessment multiple sclerosis; GNDS: Guy's neurological disability scale; UL: upper limbs; LL: lower limbs; GNDS/BR: Brazilian version

Table 2. Characteristics of the psychometric properties of the instruments included

Instrument	Psychometric properties					
	Reliability α ICC	Validity	Sensitivity	Responsitivity	Quality of the data Representativeness practicability	IRT adjustment
FSS[15]	- -	-	?	?	? No Yes	Flaws 4 items
EFS/BR[4]	? ?	?	?	?	? No Yes	?
MFIS[19]	- +	?	?	?	? No Yes	Flaws 8 items
MFIS/BR[11]	+ +	+	?	?	? No Yes	?
CPF-MS[20]	? ?	?	?	?	? No Yes	?
CPF-MS/ BR[12]	+ ?	+	?	?	? No Yes	?
FAMS[22]	+ +	-	?	?	? Yes Yes	Yes
DEFU[13]	+ -	-	?	?	? No Yes	?
GNDS[21]	+ +	+	?	+ p<0.001	? No Yes	?
GNDS/BR[10]	+ +	-	?	?	? Yes Yes	?

α: internal consistency coefficient α of Cronbach; ICC: intraclass coefficient correlation; IRT: item response theory; FSS: Fatigue Severity Scale; ESF/BR: fatigue severity scale (Brazilian version); MFIS: Modified Fatigue Impact Scale; MFIS-BR: modified fatigue impact scale (Brazilian version); CPF-MS: Cognitive and physical fatigue in MS; CPF-MS/BR: Brazilian version; FAMS: Functional Assessment Multiple Sclerosis; DEFU: functional assessment multiple sclerosis of quality of life; GNDS: Guy's neurological disability scale; GNDS/BR: Brazilian version; +: acceptable; -: unacceptable; ?: unknown data; Acceptable properties: reliability (0.70≤internal consistency ≤0.90; reproducibility>0.80), validity (correlation coefficient >0.75)

due to its complexity[1,28,29]. The fatigue is a complaint, essentially, subjective and heterogeneous, that varies among individuals due to frequency, severity, the onset ways and psychosocial conditions[2,30-32].

All analyzed instruments were developed in English and, therefore, need to be transculturally adapted so they are available in Brazil. This process allows changes in the structure of the items of an instrument and in the modeling of their domains, preserving the original hypothesis, besides solving difference on language and concept perception between countries and cultures[18,22]. All steps of such process were identified in most of the studies, except for ESF/BR and CPF-MS/BR. Thus, such instruments are more likely to have psychometric flaws and conflicting results, due to limitations as for the obtaining of equivalences in their original versions.

The representativeness of the sample as for the target population is fundamental for the quality of the instrument, for its adequate size allows generalization for the population[5,19]. Small samples in the studies of versions FSS, ESF/BR, MFIS/BR, DEFU, GNDS, CPF-MS and CPF-MS/BR impair references for comparisons on their performance.

Considering the subjective nature of the fatigue, an assessment instrument must represent what the individual really does experience, i.e., specifically for the MS[27]. Most of the analyzed instruments here developed are exclusive for individuals with MS; however, they emphasize, specially, physical and cognitive dimensions of the fatigue over other also relevant factors. Specific questionnaires must include items created clearly to qualify, define and describe fatigue within the context of similar symptoms (depression, sleep disorders, motor and cognitive performance and impact in the quality of life)[5,31-33].

The psychometric properties are criteria necessary in order to determine the methodological quality of the instruments. In order to address the basic psychometrics, an instrument must, at least, reunite evidences of reliability and acceptable validity[18]. There was little information on most properties of the instruments. The flaws in the original versions are also evident in the Brazilian ones. Despite some studies documenting this assessment, they did not meet the scientifically accepted methodological criteria in most properties, considering there is, most of the time, an ignorance of knowledge, especially in sensitivity, responsiveness and adjustment to IRT.

Reliability, validity and practicality were the most evidenced psychometric properties in the analyzed versions. The reliability was the most demonstrated one, justified by its relevance to psychometrics, for it refers to the quality of the scores of the test, suggesting how much it is free of measurement mistakes for a reproducible result[18,33]. Within the validity aspects, the construct one prevails in the versions. It constitutes a valuable way of assessing the instrument, being the confirmation that the instrument measures what it really proposes[18,19,33]. All versions have acceptable practicality versions, because they are instruments of easy and quick use.

The instruments FSS and MFIS have been the most used ones worldwide in order to assess fatigue in MS[7]. However, some limitation and psychometric flaws were identified in these instruments. They are generic instruments, considering only overall aspects of the fatigue. Studies using the statistical model of Rasch demonstrated that the FSS presented four items[34] and the MFIS, eight[28], incompatible with the fatigue measure in MS. It was reported, in this study, that the FSS instrument and its adapted version, , ESF/BR, had more flaws in demonstrating measure patterns which are acceptable among them all. Considering the current psychometric Standards, in this study, the version MFIS/BR constitutes the most recommended instrument in order to assess fatigue in MS.

The choice of an instrument depends, specially, on its purpose[9]. Given the psychometric flaws of the analyzed instruments, it is important to consider which of them have a target-dimension aimed at being assessed and the most pertinent psychometric property for such. There was a difficulty in identifying a self-report instrument, available in Brazil, which properly assesses the fatigue of MS and is an example of methodological and psychometric Standards in its conception and use. In order to assess fatigue in MS, the combined use of instruments is the best option for assessment purposes that considers different factors and psychometric adequacy.

Given the above, it is suggested that the conduction of more studies on the development or transcultural adaptation and psychometric approach of the self-report instruments are specific, multidimensional and that they address the psychometrics criteria in order to assess the fatigue in Brazilian individuals with MS.

CONCLUSION

All the analyzed instruments present scarce information on their development, transcultural adaptation and/or psychometric analysis. Despite these limitations, the MFIS/BR instrument is the most recommended one in order to assess the fatigue in MS, for it was the only one to gather reliability values and acceptable validity which ensure reliable psychometric inferences for this assessment.

The instrument CPF-MS/BR presents adequate construct validity, but with partial reliability. The GNDS/BR on the other hand is reliable in its assessment, however it does not have adequate validity parameters. The FAMS presents restriction on assessing the fatigue with partial reliability. In turn, the instrument EFS/BR should not be used to evaluate fatigue in MS, since it does not have transcultural adaptation in Brazil and the assessment of psychometric properties recognized in the literature.

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