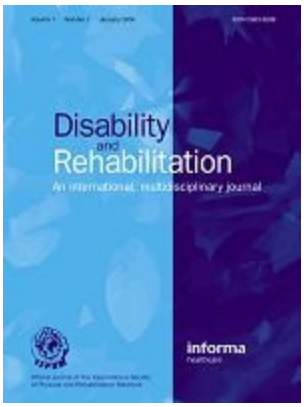

The Silhouettes Fatigue Scale: a validity study with individuals with physical disabilities and chronic pain

Journal:	*Disability and Rehabilitation*
Manuscript ID	TIDS-01-2021-182.R2
Manuscript Type:	Research Paper
Keywords:	Fatigue, Silhouettes Fatigue Scale, Validity, Assessment, Chronic pain, Disabilities

THE SILHOUETTES FATIGUE SCALE: A VALIDITY STUDY WITH INDIVIDUALS WITH PHYSICAL DISABILITIES AND CHRONIC PAIN

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Word count: 3054

ABSTRACT

Purpose: Fatigue is known to interfere with function in individuals with physical disabilities. In order to monitor changes in fatigue over time and evaluate the efficacy of treatments, psychometrically sound measures of fatigue are needed. The aim of this work was to evaluate the validity of the Silhouettes Fatigue Scale with English instructions (SFS-EN) in a sample of adults with physical disabilities living in the USA.

Methods: Individuals with medical conditions associated with physical disabilities responded to an online survey that included the SFS-EN as well as another validated measure of fatigue (PROMIS short form-4a Fatigue Scale), and measures of pain intensity and pain catastrophizing.

Results: 523 individuals participated (mean age=59.1 years; SD=11.4). Most participants were Caucasian (89%), women (59%) and unemployed (71%). Results showed strong positive correlations between both measures of fatigue, supporting the convergent validity of the SFS-EN. In addition, the magnitude of this association was significantly greater than the association between the scores of the SFS-EN and the measures of pain intensity and pain catastrophizing, supporting the former's discriminant validity.

Conclusions: The findings extend previous results supporting the SFS as a brief, easy to administer and understand, and valid measure of fatigue.

Key words: Fatigue; Silhouettes Fatigue Scale; Validity; Assessment; Chronic pain; Disabilities.

Introduction

Fatigue can be defined as a subjective multifactorial experience that has physiological, psychological and social components. It is a subjective experience that can vary from feelings of general tiredness to an overwhelming, debilitating, and sustained sense of exhaustion (1).

The causes of fatigue are not always easily identified (2). However, fatigue is common in the general population, with prevalence rates ranging from 10% to 38% (3,4), and it is often a major source of disability. Studies with non-clinical groups of adults have shown that fatigue is associated with pain, poor sleep and lower levels of quality of life (5–7). Severe fatigue is also common in individuals with chronic health conditions, including those conditions associated with physical disability (8–12). In addition, debilitating fatigue has been shown to be a common problem in individuals with chronic pain (13–15).

The assessment of fatigue can be challenging (16–18), and some generic fatigue questionnaires have been developed in an attempt to overcome these challenges (19) . Existing questionnaires have multiple items, which help to increase the reliability of the measurements. However, the use of multiple items can also contribute to assessment burden. Thus, although many existing measures have been shown to provide valid measurements of overall fatigue, they also have limitations in situations and settings where a very brief measure is needed (e.g., during hospital rounds at bedside assessments, survey research requiring very brief measures).

Recently, Miró and colleagues (20) reported on the psychometric properties of the Silhouette Fatigue Scale (SFS), a newly developed single item scale to measure overall fatigue. The results showed that the SFS was valid for assessing fatigue in a sample of elderly Spanish-speaking individuals living in Spain. However, the study was conducted with a relatively small sample (N = 70) of healthy elderly individuals. Thus, before it is possible to recommend wide use, the SFS should be studied in additional samples of individuals, including individuals with health conditions in which fatigue might be an important issue.

Given these considerations, the objective of this research was to evaluate the validity of the Silhouettes Fatigue Scale with English instructions (SFS-EN) when used in a sample of English-speaking adults with health conditions associated with physical disabilities and chronic pain living in the United States of America. If the SFS-EN scores were valid, we hypothesized positive strong and statistically significant associations between the SFS-EN scores and the scores of another validated measure of fatigue (the PROMIS-Fatigue Scale(21); i.e., *convergent validity*). We also hypothesized that the magnitude of the correlation between the scores of the SFS-EN and the scores of the PROMIS-Fatigue Scale would be significantly greater than the associations between the SFS-EN and measures of domains that are theoretically distinct from fatigue (i.e., *discriminant validity*); specifically, pain catastrophizing as assessed by the two-item version of the Catastrophizing scale of the Coping Strategies Questionnaire (CSQ; (22)) and pain intensity as assessed by a 0-10 Numerical Rating Scale. Furthermore, we expected that the results would be similar among the groups in which we planned to evaluate the convergent and discriminate validity properties of the SFS-EN, that is, in the total sample of participants and in each of the following diagnostic groups: multiple sclerosis, back pain, and spinal cord injury.

Methods

Participants

Participants were recruited from a database of adults with health conditions associated with physical disabilities that is maintained by the University of Washington, Seattle, WA. The individuals had participated in previous studies and agreed to be contacted for participation in additional research studies. A complete description of individuals in the database is provided by de la Vega and colleagues (23). In order to participate in this study, potential participants had to endorse having chronic pain (in this study chronic pain was defined as a constant or recurrent bothersome pain during the last three months, on at least half of the days) and had to have access to a computer or smartphone with an Internet connection. Participation was voluntary, and participants did not receive any compensation.

Procedures

Potential participants received emails with a brief explanation of the study objectives, a description of the survey questions, and a link to access the online survey. Individuals expressing an interest in participating and meeting the inclusion criteria were requested to sign an informed consent form. The data in this study were collected anonymously and managed using REDCap electronic data capture tools (24) hosted at the University of Washington. REDCap is a secure web-based application developed to support data collection for research studies. A total of 702 individuals provided some information and, of these, 523 completed the survey questions that are relevant to this study (i.e., that concern the measures listed below) and made up this study sample. The Institutional Review Board of the University of Washington reviewed the procedures and the content of the survey and considered the study of "minimal" risk. Thus, it was considered exempt from a full board review. Two studies have been published using data from the same dataset (23,25). However, neither of these studies used data from the Silhouettes Fatigue Scale or addressed the research questions of this study.

Measures

Demographic information. We collected information about sex, age, race, diagnosis, education, and working status using a questionnaire developed for the study (23).

Pain intensity. We used the 0 -10 Numerical Rating Scale (NRS-11) where 0 is "No pain" and 10 is "The worst pain possible" to assess average pain intensity over the previous week. NRS-11 pain intensity scores have demonstrated to provide valid and reliable information when used with adults, including individuals with disabilities and chronic pain (26,27).

Catastrophizing. The 2-item version of the Catastrophizing scale of the Coping Strategies Questionnaire (CSQ) was used to assess catastrophic thinking about pain (28). With the CSQ, respondents are requested to indicate the degree to which they experienced catastrophizing-related thoughts and feelings while in pain on a 7-point scale, ranging from 0 ("Never") to 6 ("Always") (e.g., It is terrible and I feel it is never going to be any better). Scores on this 2-item

version of the CSQ have been shown to be valid and reliable when used with individuals with chronic pain (22). In the current sample, the Cronbach's alpha of these two items was 0.84, indicating good internal consistency.

Fatigue. We used the PROMIS short form-4a Fatigue Scale (21) and the English version of the Silhouettes Fatigue Scale (SFS-EN) to measure fatigue (20). The PROMIS-Fatigue Scale has 4 items (e.g., "…I have trouble starting things because I am tired ") and respondents are asked to rate how often they experienced each fatigue response during the past 7 days using a 5-point Likert scale from 5 ("Not at all") to 1 ("Very much"). Higher scores on the PROMIS Fatigue Scale indicate greater fatigue. Previous work has shown that these PROMIS items are able to provide valid and reliable information about fatigue in different populations (29). The internal consistency (Cronbach's alpha) of the PROMIS Fatigue Scale in the current sample was excellent ($\alpha = 0.93$).

The Silhouettes Fatigue Scale (SFS) is a visual scale that was originally developed in Catalan and Spanish languages (20). It depicts 6 human silhouettes indicating increasing levels of fatigue from left to right (Figure 1). The leftmost figure represents "No fatigue" and each addition figure to the right represents gradually higher levels of fatigue, up to the sixth figure representing "A lot of fatigue." With this scale, respondents are asked to indicate the average level of fatigue experienced during the week prior to the interview by selecting the figure that best characterized the degree of fatigue that they felt. No specific instructions are given as to any specific type of fatigue (e.g., physical fatigue vs. mental fatigue). The scale is scored from 0 to 10 (0-2-4-6-8-10). Higher scores reflect more fatigue.

The SFS instructions were translated into English following a back-translation procedure to preserve the denotation and connotation of the original (30,31). This required that it be first translated from Catalan to English by a psychologist fluent in both Catalan and English which was not familiar with the scale. Next, a native professional translator translated the English version back into Catalan. Finally, this version was checked by the authors of the original SFS

questionnaire to determine if the SFS with English instructions (SFS-EN) was faithful to the original one. Since the original authors agreed with the back translated Catalan version, no additional work was required. The instructions in English for the SFS are as follows: “These silhouettes show how much a person can be fatigued. This silhouette *[pointing to left-most silhouette]* shows no fatigue. The silhouettes show more and more fatigue up to *this* one *[pointing to the right-most silhouette]*. It shows a lot of fatigue. Please, point to the silhouette that shows how much fatigued you have been during the previous week." The Flesh-Kincaid reading ease score of the instructions in English was 85.0, indicating a Flesh-Kincaid Grade level of 3.3.

[Insert Figure 1 about here.]

Statistical analysis

We first computed means and standard deviations (for continuous variables), and numbers and percentages (for dichotomous variables) of the study variables for descriptive purposes. In order to study the convergent validity of the SFS-EN, we computed a Pearson correlation coefficient between the SFS-EN ratings and the PROMIS short form-4a Fatigue Scale total scores (a “strong” correlation would be a coefficient greater than 0.51; a “medium” correlation would be a coefficient between 0.31 and 0.50; a “weak” correlation would be a coefficient between 0.11 and 0.30; and a “less than weak” correlation would be a coeficient between 0.00 and 0.10 (32)). In order to evaluate the discriminant validity of the SFS-EN, we conducted a Steiger’s z test (33) comparing the magnitude of the correlation between the SFS-EN and the PROMIS short form-4a Fatigue Scale scores with the magnitude of the correlations between: (1) the SFS-EN and the two-item version of the Catastrophizing scale of the Coping Strategies Questionnaire scores, and (2) with the NRS-11 pain intensity ratings scores. The analysis was set for dependent groups with overlapping variables, one-tailed, alpha 0.05 and confidence level of 0.95. These analyses were conducted both for the total sample of participants and for individuals from the sample in each of the following diagnostic groups:

multiple sclerosis, back pain, and spinal cord injury. All analyses were conducted using the Statistical Package for Social Sciences for Windows version 25.0 (SPSS Inc., Chicago, IL, USA).

Results

Participants

A total of 523 participants provided complete data for the questionnaires used in the analyses. See Table 1 for a description of the sample.

[Insert Table 1 about here]

The mean age of the participants was 59.1 years (SD = 11.4 years), 310 (59%) were women and most were Caucasian (469; 89%). Participants reported one or more of the following diagnoses: back pain (n = 225), multiple sclerosis (n = 199), osteoarthritis (n = 107), spinal cord injury (n = 101), amputation or limb loss (n = 76), diabetes (n = 69), post-polio syndrome (n = 64) and muscular dystrophy (n = 33), cancer (n = 16), fibromyalgia (n = 11), traumatic brain injury (n = 10), Stroke/Cerebral vascular accident (n = 7), Parkinson disease (n = 2). The most frequent diagnoses among participants reporting just one diagnosis were: multiple sclerosis (n = 127), back pain (n = 122), and spinal cord injury (n = 65). These were the diagnostic groups selected for the planned sub-group analyses.

The majority of the participants in the sample (71%) were retired, on disability, or unemployed due to pain, although 24% were working full or part time. The education level was high, with 83% of participants reporting that they had attended university or graduate school. In the total sample, mean pain intensity was 5.27 (SD = 1.93), and Pain Catastrophizing was 4.24 (SD = 3.30). In addition, in the total sample, Mean T-score on the PROMIS Fatigue scale was 50.00 (SD = 10.00), whereas mean score on the SFS-EN was 3.72 (SD = 1.28). There were no statistically significant differences in fatigue levels among the participants in the three diagnostic groups examined for both measures of fatigue (i.e., multiple sclerosis, back pain and spinal cord injury). Tables 1 and 2 summarize the descriptive information of the total sample, and the

information about the clinical variables included in the study both for the entire sample, and each of the three diagnostic groups (i.e., multiple sclerosis, back pain, and spinal cord injury).

[Insert Table 2 about here]

Convergent and Discriminant Validity of the SFS-EN

The convergent validity of the SFS-EN was supported by a statistically significant strong positive correlation between the scores on the SFS-EN and scores on the PROMIS short form-4a Fatigue Scale, both when considering the sample of participants as a whole (r = .71, p < .001), and the three diagnostic groups individually: multiple sclerosis (r = .61, p < .001), back pain (r = .83, p < .001), and spinal cord injury (r = .79, p < .001).

Discriminant validity was supported by the magnitude of the correlation between the scores on the SFS-EN and the scores on the PROMIS short form-4a Fatigue Scale being statistically significantly stronger than the magnitude of the correlations between the scores on the SFS-EN and the total scores on the 2-item version of the Catastrophizing scale of the CSQ and on the NRS-11. This was the case both when considering the sample of participants as a whole ([CSQ: r = .71 vs r = .26; z = 11.41, p < .0001] and [NRS-11: r = .71 vs r = .37; z = 9.57, p < .0001]), and the three diagnostic groups individually: (1) multiple sclerosis ([CSQ: r = .61 vs r = .16; z = 4.34, p < .0001] and [NRS-11: r = .61 vs r = .22; z = 4.13, p < .0001]); (2) back pain ([CSQ: r = .83 vs r = .31; z = 5.28, p < .0001] and [NRS-11: r = .83 vs r = .63; z = 2.80, p < .005]); and (3) spinal cord injury ([CSQ: r = .79 vs r = .33; z = 5.88, p < .0001] and [NRS-11: r = .79 vs r = .39; z = 5.68, p < .0001]) (see Table 3).

[Insert Table 3 about here]

Discussion

The primary aim of this study was to further evaluate the convergent and discriminant validity of the Silhouettes Fatigue Scale (SFS) as a measure of fatigue. The findings are consistent with those reported in Miró and colleagues' study (20), which supported the validity of the SFS when used in a sample of healthy Spanish-speaking elderly individuals living in Spain. The

current findings also extend the knowledge as they provide additional evidence on the validity of the SFS-EN scores with a very different sample of individuals (i.e., English-speaking participants, living in the USA, and with physical disabilities and chronic pain).Moreover, the findings were consistent across diagnostic groups (i.e., multiple sclerosis, back pain and spinal cord injury). Importantly, the results of the Flesh-Kincaid reading ease score showed that the SFS-EN is also very easy to understand.

The SFS is distinct from existing measures of fatigue in important ways. First, the SFS performs similarly across samples. Research has shown that items in the questionnaires of fatigue may behave in very different ways depending on the sample. For example, Johansson and colleagues (34) found that 4 out of the 7 items included in the 7-item version of the Fatigue Severity Scale functioned differently between the three samples in which this was used (i.e., Multiple sclerosis, Stroke, and HIV/AIDS). The fact that, in this study, the SFS behaved equally across diagnostic groups – at least with respect to the groups that were evaluated – suggests that it can be used indistinctively with adults with physical disabilities, regardless of their diagnoses. This provides additional support for the validity of the SFS, and is an important advantage compared to some fatigue scales.

Second, all of the existing fatigue scales require a minimum level of reading proficiency or comprehension of the items included. The SFS is a visual scale, and is the only visual scale available to measure fatigue, to the best of our knowledge. Because the SFS does not have written words in the response options, it may be more easily understood by people who have limited or even no literacy, thus making potentially more useful than other fatigue scales in these populations. Consistent with this idea, visual rating scales have been found to be preferred over other rating scales. For example, the Faces Pain Scale –Revised (35), has been found to be preferred over numerical or verbal scales in studies with elderly individuals (36) and in young people (37) . However, we are not able to say if (and for whom) the SFS is a preferred

measure of fatigue, as this was not assessed in the current study. Future studies to address this issue are warranted.

Third, being a single-item rating scale, the SFS allows the respondent to rate her or his level of fatigue easier and faster than with other currently available questionnaires. All the other validated fatigue scales have more than one item (and some have many items; e.g., (38,39)). Although measures with more items tend to have more reliability, all else being equal, having multiple items may also limit their utility in situations and settings where a very brief and easy to understand measure is needed.

This study has some limitations that should be taken into account when interpreting the results. First, participants were a group of individuals with a variety of medical conditions associated with physical disability and chronic pain that were motivated to participate in research. We do not know the extent to which the sample is representative of other individuals with thesame health conditions. It would be important to replicate the study with additional samples of individuals, including those with other chronic health conditions, where fatigue is also important (e.g., individuals with cancer). Second, we did not randomize the presentation of the fatigue scales. Therefore, we are not able to determine whether there were any order effects on the ratings provided by the study participants. Nevertheless, we found no differences caused by the order in which the scales were provided in a previous study(20). Finally, there are some important psychometric properties of the SFS that were not examined here, including its sensitivity to change over time or test-retest reliability characteristics. Future studies to evaluate these additional properties of the SFS are needed, including the properties of the 6 images on the scale, to see if individuals with different diagnoses rate the scale differently, or whether responses are related to other characteristics like gender or age, among others.

Despite the study's limitations, the findings suggest that the scores provided by the SFS-EN are a valid measure of fatigue that can be used in samples of adults with health conditions associated with disability and chronic pain. Research studying predictors and consequences of

fatigue, or the effects of behavioral and pharmacological interventions targeting fatigue, could take advantage of the unique characteristics of the SFS. In conclusion, the findings support the SFS as a brief and easy to administer and understand scale that can be used in situations and settings where assessment burden is a significant issue, and in samples with English-, Spanish-, and Catalan-speaking individuals.

Disclosure statement: The authors declare no financial or other relationships that might lead to a conflict of interest related to this study.

Funding

JM's work is supported by the Spanish Ministry of Economy, Industry and Competitiveness (RTI2018-09870-B-I00; RED2018-102546-T), the European Regional Development Fund (ERDF), the Government of Catalonia (AGAUR; 2017SGR-1321), Fundación Grünenthal (Spain), Universitat Rovira i Virgili (PFR program), and ICREA-Acadèmia. RV's work is supported by the Spanish Ministry of Science and Innovation with a Ramón y Cajal contract (RYC2018-024722-I).

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Table 1. Descriptive data of the study's participants (entire sample, N = 523).

Variable	Percent or Mean (SD)	N
Age, years	59.1 (11.4)	478
Sex		
Men	34%	176
Women	59%	310
Diagnosis*		
Amputation	14%	76
Back Pain	43%	225
Cancer	3%	16
Diabetes	13%	69
Multiple sclerosis	38%	199
Spinal cord injury	19%	101
Muscular dystrophy	6%	33
Osteoarthritis	20%	107
Parkinson disease	0.4%	2
Post-polio syndrome	12%	64
Stroke/Cerebral Vascular		
Accident	1%	7
Traumatic Brain injury	2%	10
Fibromyalgia	2%	11
Education		

Primary school	1%	2
High or tech school	17%	86
Some college	25%	129
College graduate	28%	149
Graduated school	30%	165
Employment status		
Employed full-time	14%	72
Employed part-time	10%	54
Vocational training part-time	1%	4
Retired	42%	222
Homemaker	3%	19
Unemployed due to pain	10%	55
Unemployed for other Reasons	18%	93
Ethnicity		
Black/African American	3%	15
Asian	1%	3
White/Caucasian	89%	469
Native Am./Alaska Native	1%	3
Pacific Islander	1%	2
Other	2%	10
Marital status		
Married/ Living with SO	66%	312
Separated/ Divorced	19%	90

Never married	13%	61
Widowed	3%	12

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* Participants reported one or more of the diagnosis listed

Note: SD= Standard Deviation; SO = Significant other

Table 2. Variables included in the study

	Entire Sample (N=523)	Multiple sclerosis (N=127)	Back pain (N=122)	Spinal cord injury (N=65)
Variable	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Fatigue Scores (SFS)	3.72 (1.28)	3.87 (1.20)	3.75 (1.28)	3.48 (1.41)
Fatigue Scores (PROMIS)	50 (10)	47.73 (8.94)	49.39 (9.62)	55.07 (10.62)
Average pain Intensity	5.27 (1.93)	4.88 (1.85)	5.45 (1.92)	4.92 (2.02)
Catastrophizing	4.24 (3.30)	3.62 (3.20)	5.07 (3.07)	4.14 (3.03)

Note: SD= Standard Deviation; SFS=Silhouettes Fatigue Scale; PROMIS= PROMIS short form-4a Fatigue Scale

Table 3. Correlation coefficients between the variables in the study

Group	Variable	PROMIS	NRS-11	CSQ
Entire sample	SFS	.71**	.37**	.26**
	PROMIS		.38**	.31**
	NRS-11			.40**
MS	SFS	.61**	.22*	.16
	PROMIS		.25**	.15
	NRS-11			.32**
BP	SFS	.83**	.63**	.31*
	PROMIS		.49**	.34**
	NRS-11			.50**
SCI	SFS	.79**	.39**	.33**
	PROMIS		.43**	.24**
	NRS-11			.41**

Note: SFS= Silhouettes Fatigue Scale; PROMIS= PROMIS short form-4a Fatigue Scale, NRS-11= Numerical Rating Scale-11; MS= Multiple sclerosis; BP= Back pain; SCI= Spinal cord injury

** p < 0.01; *p < 0.05

Figure captions:

Figure 1. Silhouettes Fatigue Scale (SFS). © Miró, 2015, reproduced with permission.

IMPLICATIONS FOR REHABILITATION

- Fatigue is common in adults with physical disabilities and chronic pain.
- The Silhouettes Fatigue Scale (SFS) is a new single-item measure of general fatigue.
- Findings show that the SFS with English instructions (SFS-EN) is an easy to understand measure.
- Results support the convergent and discriminant validity of the SFS-EN score in adults with physical disabilities and chronic pain.

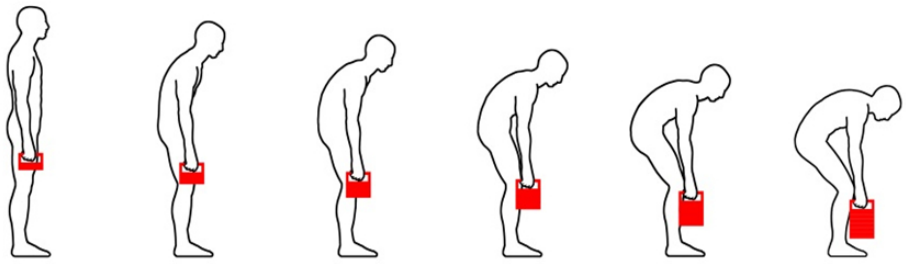

Figure 1. Silhouettes Fatigue Scale (SFS). © Miró, 2015, reproduced with permission