Cross-Cultural Adaptation and Validation of the Fatigue Severity Scale among Kannada-speaking Individuals with Neurological Disorders: A Cross-Sectional Study in South India

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ABSTRACT

Purpose: *The Fatigue Severity Scale (FSS) has been translated and validated in many languages across the world. Since it is a self-reported scale, it is necessary for clients to understand the components in order to quantify them. However, to date, the version in Kannada, the language spoken locally in the state of Karnataka in South India, has not been validated. This study aimed to perform cross-cultural adaptation and determine concurrent validity and test-retest reliability of the Kannada version FSS among Kannada-speaking individuals with neurological disorders.*

Method: *A cross-sectional study was conducted in the neuro-rehabilitation unit of a tertiary care hospital in southern Karnataka. Cultural adaptation of the scale was targeted at the Kannada-speaking population. It was pilot tested among 30 individuals with neurological conditions. The adapted scale was then evaluated for concurrent validity along with the Visual Analogue Fatigue Scale, by correlating the scores of fatigue assessed by both the scales among 83 participants. Reassessment of fatigue was done on all the participants the following day, to determine the test-retest reliability of the Kannada-version FSS scale among individuals with neurological disorders.*

Results: *The Kannada version of the Fatigue Severity Scale showed an excellent correlation with Visual Analogue Fatigue Scale scores ($r = 0.71$, $p<0.001$) and good intra class correlation coefficient ($\alpha=0.92$) with reassessment scores."*

The fatigue scores showed no significant difference ($F=0.9$, $p=0.5$) when compared across various neurological conditions."

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Conclusion and Implications: *The culturally-adapted Kannada version of the Fatigue Severity Scale has proved to be a valid and reliable tool to assess severity of fatigue among Kannada- speaking individuals with neurological disorders. It could therefore be used routinely as an efficient tool for the effective assessment and management of fatigue in clients with all types of neurological conditions.*

Key words: *fatigue, nervous system diseases, reproducibility of results*

INTRODUCTION

Fatigue is a multifaceted concept and a commonly used term associated with several interpretations, disciplines and meanings. Clinically, fatigue is described as an "overwhelming sense of tiredness at rest, exhaustion with activity, lack of energy during daily tasks or lack of endurance or vigour" (Kalkman, Zwarts, Schillings, van Engelen & Bleijenberg, 2008). It is challenging to describe fatigue because of its subjective nature and the inability to differentiate between muscle weakness, normal tiredness, daytime sleepiness, cognitive fatigability and depression, yet it is a prominent symptom in multiple medical and neurologic disorders (Al-Sobayel et al., 2016). Around 5% - 45% of community and primary care studies report fatigue as a major symptom which persists for up to six months in 2% -11% of the population (Kluger, Krupp & Enoka, 2013).

Fatigue is a dominant symptom in many neurological conditions including Stroke, Myasthenia gravis, Multiple Sclerosis, Traumatic Brain Injury, and Parkinson's disease which is independent of sleep deprivation, mood disorders and medications (Kluger et al., 2013). However, because of its uncertain nature and the difficulty in describing it as a single entity, assessing it is a problem (Al-Sobayel et al., 2016).

Assessment of fatigue subjectively can be carried out through various methods including client-reported questionnaires, maintaining a diary or through interviews. Objective measurement mainly focuses on physiological process or performance (Laranjeira, 2012). Client-reported questionnaires have been proven effective in determining fatigue (Sharma & Sheth, 2019). Various questionnaires like Fatigue Severity Scale (FSS), Visual Analogue Fatigue Scale (VAFS), and Multidimensional Fatigue Inventory are developed and used to measure fatigue symptoms (Hewlett, Dures & Almeida, 2011). The most commonly recommended fatigue-specific scale is the FSS (Friedman et al., 2010). Published in 1989, it covered physical, social and cognitive aspects of fatigue in clients with multiple sclerosis and systemic lupus erythematosus (Krupp, LaRocca, Muir-Nash &

Steinberg, 1989).

The psychometric properties of FSS showed good validity, reliability and high internal consistency in various disease populations (Whitehead, 2009). This scale is widely used in clinical practice and research, and has been translated into a number of languages including Arabic (Al-Sobayel et al., 2016), Brazilian (Valderramas, Feres & Melo, 2012), Dutch (Rietberg, Van Wegen & Kwakkel, 2010), and Finnish (Rosti-Otajärvi, Hämäläinen, Wiksten, Hakkarainen & Ruutiainen, 2017) to name a few. In India, linguistic translation and adapted versions are available in Hindi/ Punjabi (Paul et al., 2016) and Gujarati (Sharma & Sheth, 2019). Though a Kannada version of FSS is available (translated by Dr Lauren Krupp along with MAPI Institute, which was obtained through personal communication dated 12th December, 2018), it has not been tested on people who speak the Kannada language. Assessment of fatigue is directed towards the specific client group, and cultural factors may have a significant influence on the assessment. Hence, translated versions need to be validated before they can be used for assessment in the specific population (Rosti-Otajärvi et al., 2017). To date, the Kannada version FSS has not been culturally adapted or validated among the local Kannada-speaking population.

Objective

The aim of this study was to cross-culturally adapt and pilot test the FSS among Kannada- speaking individuals with neurological disorders, and further evaluate its concurrent validity and test- retest reliability.

METHOD

Study Design

The author of the original FSS was contacted and permission to use, culturally adapt and validate the Kannada version of the FSS was obtained.

A cross-sectional study was then conducted in two phases.

Study Sample

All the participants were recruited from the neuro-rehabilitation unit of a tertiary care hospital in southern Karnataka.

Clients admitted in the hospital with neurological conditions and complaining of fatigue were included if they were:

- Older than 18years,
- Cognitively sound, and
- Able to read Kannada.

Excluded were those:

- With communication disorders,
- Undergoing treatment with immunomodulatory drugs,
- With co-existing disorders of other systems influencing fatigue, and
- Unable to understand simple instructions.

Tools

Fatigue Severity Scale (FSS) – This is a unidimensional 9-item client-reported scale which measures the physical, social and cognitive aspects of fatigue. The questions are mainly associated with how fatigue interferes with certain activities, and rates the severity on a 7-point Likert scale where '1' indicates 'strongly disagree' and '7' indicates 'strongly agree'. The overall score will be the average of the scores of the individual items. The total score of 4 or >4 will indicate fatigue; the higher the score, the greater the fatigue severity (Learmonth et al., 2013).

Study participants were asked to rate their level of fatigue during the past week.

Visual Analogue Fatigue Scale (VAFS) - This is a 10cm horizontal line with descriptions "No fatigue" and "Very severe fatigue" written at either end. Participants are asked to mark the place on the line that they think defines their fatigue level best. The distance is then measured from the "No fatigue" end up to the client's mark. Scores range from '0' to '100'mm; the higher the score, the greater the levels of fatigue (Tseng, Gajewski & Kluding, 2010).Study participants were asked to mark the place on the line which they thought best indicated their current level of fatigue.

Data Collection

Phase 1: Cross cultural adaptation and pilot testing of the scale

Five individuals with different educational backgrounds, fluent in Kannada and with good understanding of the language, were selected for the process of cultural validation. They were asked to read the items and scoring criteria of the previously translated Kannada version of FSS. All the individuals were asked to comment on the clarity, comprehensiveness and simplicity of the scale items and scoring criteria. Based on their comments, the semantic, idiomatic, experiential and conceptual equivalence of the Kannada version of FSS was assessed and the required modifications were made.

The culturally-adapted Kannada version FSS was administered to 30 participants (Beaton, Bombardier, Guillemin & Ferraz, 2000) with different neurological conditions. The items and method of scoring were explained in Kannada. Participants were asked to mark the amount of interference with their activities that fatigue caused, which would indicate their level of fatigue. Adequate time was provided for all of them to complete the scale. The filled-out forms were collected and stored. During the pilot testing, frequency of responses, participants' ability to understand the questions and time taken to complete the scale were noted to evaluate the administrative burden of the scale.

Data Analysis

The data was analysed and the values obtained were used to estimate the sample size for the next phase of the study. The sample size calculated was 35 for concurrent validity and 83 for the test-retest reliability; however highest sample size of 83 was used for both the phases. The formulae used to calculate sample size were as follows:

Concurrent validity: $n= [Z\alpha+Z\beta]^2 + 3/ [C (r)]^2 = 35$ where, $c (r) = 1/2\log_e (1+r / 1-r)$, $Z\alpha = 1.96$, $Z\beta = 0.84$ and $r = 0.5$.

Test-retest reliability: $n= Z\alpha^2\sum^2 / d^2 = 83$, where, $Z\alpha = 1.96$, $\sum = 0.7$ and d (precision) =15 %.

Phase 2a: Concurrent validity

Selection of participants for these phases of the study was done as mentioned above. Detailed information regarding the study was provided to all the

selected participants, after which their written informed consent was obtained. Demographic details of all the included participants were collected and they were then assessed for fatigue using Kannada version FSS and VAFS.

The participants were instructed to read the items of the Kannada version FSS and score according to the level of their fatigue, as explained earlier. To determine concurrent validity, they were all asked to grade their fatigue level using VAFS. FSS and VAFS were used alternately on participants to eliminate the sequence bias. The fatigue scores from both the scales were entered and used to analyse the concurrent validity of the Kannada version FSS against the VAFS.

Phase 2b: Test-retest reliability

All the participants with neurological disorders, who were included for concurrent validity testing, were included for the test-retest reliability as well. The participants were visited again after one day and the procedure was repeated to assess the severity of fatigue using Kannada version FSS. Since fatigue as a symptom is highly variable with time and can be altered with prevailing experience, intervention or mood, this time interval was chosen (Laranjeira, 2012; Chang, Gillespie & Shaverdian, 2019). The items within the scale were rearranged during the second assessment to eliminate the learning effect and sequence bias. Even though the clients tried to recollect the order of the items during the first assessment, they would not be able to score in a similar way due to changes in the presented order during the second assessment. This will possibly eliminate learning effect and sequence bias (Ngo, Stupar, Côté, Boyle & Shearer, 2010). The time of assessment was kept the same for both the assessments on consecutive days. Data obtained from both the sessions were entered and used to analyse the test retest reliability of the Kannada version FSS.

Data Analysis

SPSS version 16 was used for data analysis. Descriptive statistics were used to describe all the demographic variables. Spearman's Rank Correlation Coefficient was used to determine the concurrent validity of Kannada version FSS, and Intra-class Correlation Coefficient (ICC) was used to determine the scale's test-retest reliability. Mann-Whitney U test and One-way ANOVA were used to compare the FSS scores between gender, sleep time, duration, age, and across different neurological conditions. Level of significance was set at $p<0.05$ for all the analyses.

Ethics Approval

Approval was sought from the Institutional Ethics Committee, Kasturba Hospital, Manipal, Karnataka (IEC No: 103/ 2019), and the trial was registered under Clinical Trial Registry of India (CTRI/2019/04/018730) prior to recruitment of the first participant for the study.

RESULTS

Cross-Cultural Adaptation and Pilot Testing

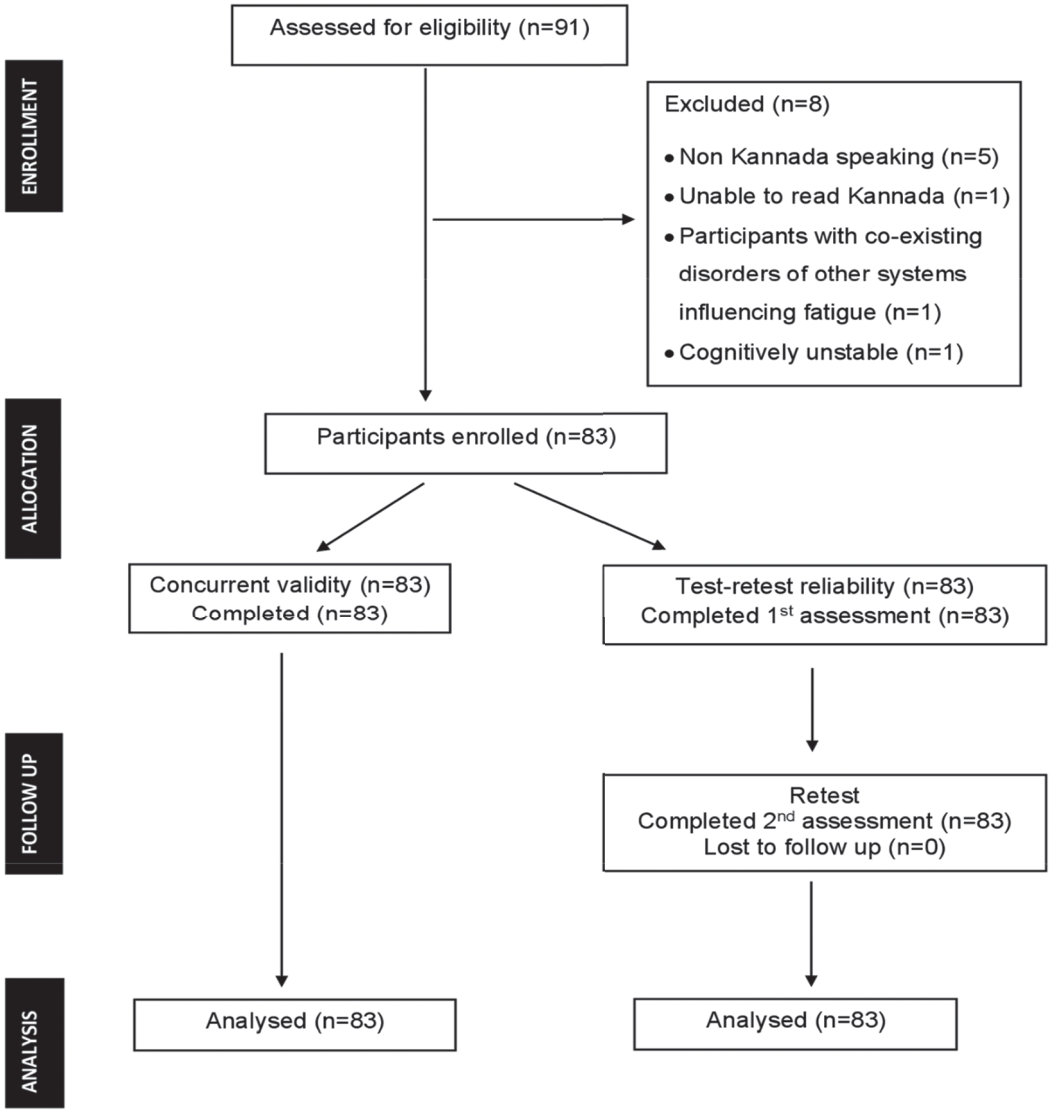
All the 5 individuals selected for cultural adaptation were able to comprehend the items and scoring criteria. They reported that all the items in the scale were simple and clear enough to be understood by any individual who could speak basic Kannada. However, 4 of these 5 individuals suggested the substitution of a synonym for the word *"satatavaagi"* ("sustained") in the 6th item of the scale, as it is not commonly used and is a little ambiguous. Hence the word *"nirantara"* ("continuous") was added, as it is simpler, commonly used and easily understood by the Kannada-speaking population. However, the translators felt that it was not necessary to add that word in the English version, as both words mean the same in English. Back translation to English was not considered necessary, since the addition of the synonym in Kannada did not change the meaning of the item. The Kannada version of the Fatigue Severity Scale was thus adapted by incorporating the change in item 6; this was further subjected to pilot testing.

The 30 participants included in the pilot study, with a mean (SD) age of 53.8 (11.7) years, had different neurological conditions: stroke (n=13), neuropathy (n=6), spinal cord diseases (n=3) and others (n=8). The majority of them were able to score all the items in the scale without any difficulty, except for item 1 and item 8. One participant was not able to understand the meaning of the word "motivation" in item 1, and two participants were not able to understand the meaning of "three most disabling symptoms" in item 8 of the scale. However, all the three participants were able to score these items with minimal prompting and cues. Hence, the frequency for all the items in the scale was 100%. The average time taken by the participants to complete the questionnaire ranged from 5 - 10 minutes. As the problems encountered during the pilot testing were very minimal, further changes were not made in the scale. Descriptive analysis was done to calculate the mean and SD of the total fatigue scores of all participants.

Concurrent Validity and Test-Retest Reliability of the Scale

Of the 91 individuals who were screened for eligibility, 83 participants were recruited. The selection procedure of participants in this phase of the study is shown in Figure 1).

Figure 1: Flow of Participants in the study



Demographic characteristics of the study participants are listed in Table 1.

Table 1: Demographic characteristics of study participants (n=83)

Characteristics	Value n (%)	Mean± SD
Age in years		51.1 ± 14.6
Gender		
Male	43 (51.8)	
Female	40 (48.2)	
Level of Education		
No schooling	2 (2.4)	
Primary school	54 (65.1)	
Secondary school	15 (18.1)	
Degree	10 (12.0)	
Post-graduation	2 (2.4)	
Marital Status		
Single	8 (9.6)	
Married	75 (90.4)	
BMI		22.6 ± 3.4
Employment		
Employed	39 (47.0)	
Not employed	44 (53.0)	
Diagnosis		
Stroke	38 (45.8)	
Neuropathy	14 (16.9)	
Spinal cord diseases	12 (14.5)	
Myopathy	5 (6.0)	
Others	14 (16.9)	
Disease Duration (in days)		549 ± 1523
Comorbidities		
Present	53 (63.9)	
Absent	30 (36.1)	
Sleep duration (in minutes)		490 ± 65.4

n - Sample size; SD - Standard deviation

Figure 2 describes the correlation between the Kannada version FSS scores and VAFS scores. There was statistically significant moderate correlation between the scores of the two scales ($r=0.71$, $p<0.001$).

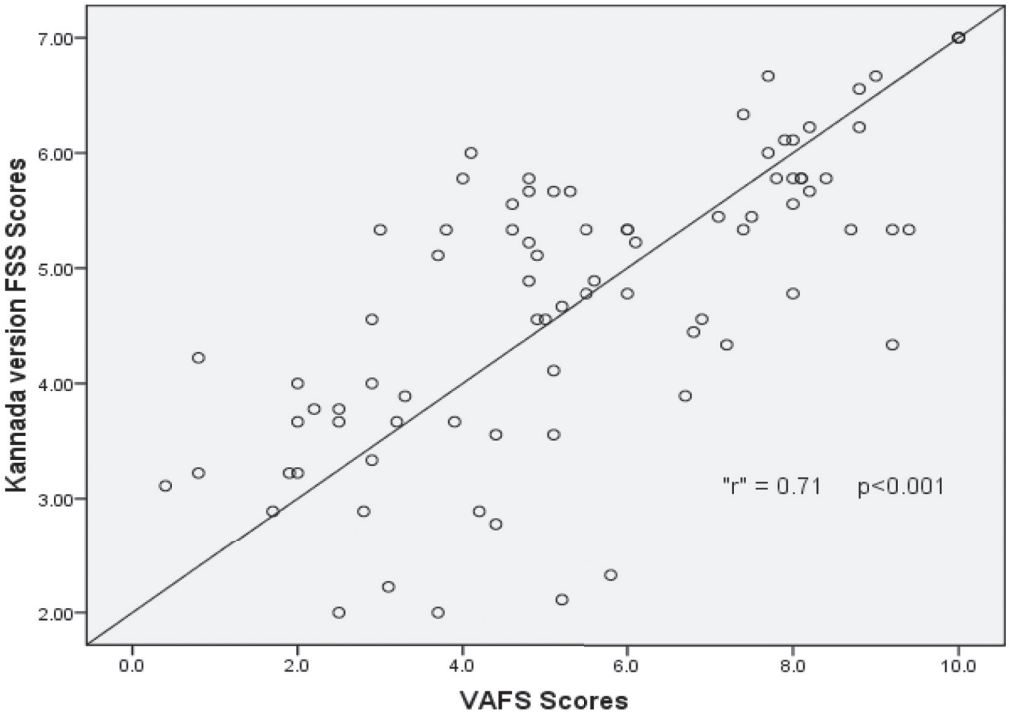


Figure 2: Correlation between the Kannada version FSS scores and VAFS scores

ICC of 0.92 with CI – 0.89-0.95 indicates excellent test-retest reliability of the Kannada version FSS. The ICC values of individual items and the total scores of the scale are listed in Table 2.

Table 2: ICC values for individual items and total scores of FSS

Items	Kannada Version FSS Mean Scores		ICC α (95% CI)
	Test	Retest	
1	5.7	5.3	0.80 (0.70 – 0.88)
2	4.6	4.4	0.78 (0.64 – 0.86)
3	3.2	3.2	0.83 (0.75 – 0.90)
4	5.1	5.3	0.80 (0.69 – 0.87)
5	4.7	4.0	0.57 (0.33 – 0.71)
6	5.2	5.2	0.77 (0.63 – 0.85)
7	4.8	4.8	0.73 (0.60 – 0.82)
8	4.8	4.2	0.86 (0.78 – 0.90)
9	4.8	4.7	0.74 (0.60 – 0.83)
Total	4.8	4.6	0.92 (0.88 – 0.95)

ICC- Intra-class Correlation Coefficient; FSS-Fatigue Severity Scale; CI- Confidence interval

No significant difference was observed when fatigue scores were compared across various neurological conditions. Mean scores of the Kannada version FSS for different neurological conditions are shown in Figure 3.

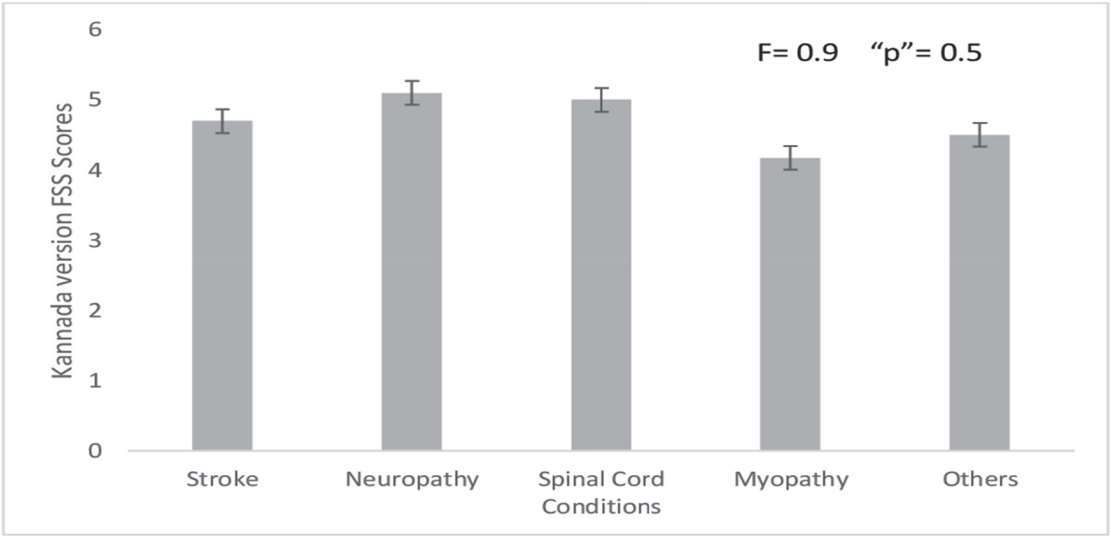


Figure 3: Mean scores of the Kannada version FSS for different neurological conditions.

The Kannada version FSS scores showed no correlation with disease duration, age, sleeping hours or gender of the participants with neurological conditions. The correlation coefficient values of various parameters with the Kannada version FSS is given in Table 3.

Table 3: Correlation of FSS scores with age, gender, sleep time and duration of the neurological conditions

Parameters	Mean (SD)	"r" value	"p" value
Duration	4.8 (1.26)	0.03	0.8
Age	4.8 (1.27)	0.23	0.04
Gender	4.7 (1.26)	0.20	0.8
Sleep time	4.8 (1.27)	0.07	0.4

SD- Standard deviation

DISCUSSION

Cross-cultural adaptation of self-reported scales in vernacular languages is of

great importance because the ability to understand the items in the scale is required for scoring appropriately, more so in self-explaining symptoms like fatigue (Beaton et al., 2000). Cultural adaptation of the scale was done with necessary adjustments targeted at the Kannada- speaking population in the present study. This ensured that the scale could be clearly perceived and comprehended by Kannada-speaking individuals.

The pilot testing of the Kannada version FSS among the Kannada-speaking population showed that the items within the scale were easily understood, indicating the clarity, feasibility and applicability of the scale. Furthermore, validity and reliability assessment of the scale revealed that it was an appropriate measure to quantify fatigue in the Kannada- speaking population with neurological conditions.

The results of concurrent validity are in line with the study done by Krupp et al. (1989) which showed moderate correlation of the FSS scores with VAFS scores among clients with Multiple Sclerosis and SLE. Similarly, Schanke et al. (2002) found FSS scores were correlated with VAFS among polio survivors. These results suggest that the Kannada version of this scale was able to detect fatigue as adequately as VAFS. However, evaluating fatigue among those with neurological conditions will be more effective with FSS due to the descriptions of nine different situations presented within the scale.

Test-retest reliability analysis of the Kannada version FSS showed good correlation and homogeneity among the items within the scale (α=0.92). The findings of the present study complemented the results of previous studies done in India, e.g., in Hindi/Punjabi by Paul et al. (2016) and in Gujarati by Sharma and Sheth (2019), which showed good reliability in their respective populations. This suggests that the items within the scale reflected similar meanings and agreement during repeated evaluations of fatigue; and hence the FSS Kannada version could be used more conveniently to grade fatigue.

Fatigue is considered as an important contributor to poor quality of life (Havlikova et al., 2008). There are several factors, including duration of the disease, age, depression, existing comorbidity, sleep duration and so on among different neurological conditions which are assumed to contribute to fatigue (De Groot, Phillips & Eskes, 2003) . Identification of factors that contribute to fatigue is important because it will lead to a better assessment and management of the symptom. In the current study, the diagnosis of participants did influence fatigue;

hence those diagnosed with neuropathy and spinal cord diseases showed more fatigue scores than other neurological conditions. These results are supported by earlier studies which revealed high prevalence of fatigue among clients with neuropathy (80%) (Merkies, Schmitz, Samijn, van der Meché & van Doorn, 1999; Merkies & Kieseier, 2016) and spinal cord diseases (37.2%) (Cudeiro-Blanco et al., 2017). Despite the absence of any proven reasons, demyelination and weakness in neuropathy could be the major factors for inducing fatigue in these populations (Garssen, Schillings, Van Doorn, Van Engelen & Zwarts, 2007); White, van Doorn, Garssen & Stockley, 2014). Similarly, sensory loss, pain and depression associated with spinal cord diseases could influence fatigue (Cudeiro-Blanco et al., 2017). These results are contrary to the belief of the current authors who anticipated greater amount of fatigue in stroke survivors than in those with other conditions. Even though post-stroke fatigue is highly prevalent, ranging from 25%-85% (Cumming, Packer, Kramer & English, 2016), the amount of fatigue may vary with type, severity and chronicity of the condition.

Despite more fatigue in chronic clients compared to acute and sub-acute phases, duration of the disease did not show any correlation with the fatigue severity scores. These results are contrary to an earlier study, which showed that increased duration of the disease contributed to fatigue in clients with stroke, brain injury and Parkinson's disease (de Groot et al., 2003). In the current study, the majority of participants admitted in the hospital were in the acute phase of a neurological condition and hence the data could have been skewed.

Factors including age and gender were assumed to affect the severity of fatigue; however, no correlation was seen with FSS scores in this study. Age could not be the sole factor for the presence and severity of fatigue, as perception of fatigue and fatigability increases with age but ability to recruit the muscle or firing rate is independent of age (Kalkman et al., 2008). Since FSS measures only the physical, social and cognitive aspects of fatigue (Krupp et al., 1989) and not the perceptual aspect, it might not be correlated to fatigue severity. The lack of association between fatigue severity scores and gender could be due to neurological conditions of the participants involved in the current study, which affected both genders equally.

Sleep disturbances are commonly observed in neuromuscular disorders, mainly due to the inability to change the position frequently at night, muscle twitches, jerks and disordered breathing due to involvement of the respiratory muscles. The common complaints reported by these clients were fatigue (83%) and daytime sleepiness (63%) (Labanowski, Schmidt-Nowara & Guilleminault, 1996).

However, this study did not show any association with sleeping hours as all the participants had an average sleep duration of eight hours per day, irrespective of different fatigue levels. Further lack of association could be explained because of the smaller number of participants with neuromuscular disorders. Several studies involving clients with recent stroke (Choi-Kwon, Han, Kwon & Kim, 2005) and Multiple Sclerosis (Armutlu et al., 2007; Labuz-Roszak, Kubicka-Baczyk, Pierzchala, Machowska-Majchrzak & Skrzypek, 2012) showed significant association of fatigue with depression. However, this could not be ascertained as the current study did not assess depression in participants. The inclusion of participants with all types of neurological conditions who were complaining of fatigue is considered as the strength of the study.

Limitations

Depression, which is considered to be one of the important factors resulting in fatigue, was not assessed in the study. Future studies could determine the association of FSS scores with depression in neurological conditions. Since there was a short time period (one day) between test and retest, there may have been a learning effect even though the items were rearranged in the FSS to limit the effect during the retest.

CONCLUSION

The Kannada version of the FSS has been culturally adapted to assess fatigue in the Kannada-speaking population and is a reliable and valid tool to assess severity of fatigue among individuals with neurological disorders in this linguistic population. In fact it could be used routinely as an efficient tool for effective assessment and management of fatigue in clients with all types of neurological conditions. The scale can be subjected to other psychometric properties such as responsiveness, to strengthen its clinical usefulness in this population.

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