Cultural Adaptation and Preliminary Validation of the Proxy-Rated Sinhala Version of the Stroke and Aphasia Quality of Life Generic Scale–39

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ABSTRACT

BACKGROUND: Health-related quality of life (HRQOL) is an important measure that enables evaluation of rehabilitation outcomes. Stroke and Aphasia Quality of Life Generic Scale–39 (SAQOL-39g) is a disease-specific questionnaire that measures HRQOL of patients with stroke. This study was conducted to adapt the preliminary version of proxy-rated Sinhala version of the SAQOL-39g.

METHODS: The study was conducted with the participation of 115 proxies of the patients with stroke. The SAQOL-39g was translated and back translated, and culturally adapted by evaluating the items of the questionnaire. The culturally adapted scale was evaluated for its internal consistency, test-retest reliability, and validity.

RESULTS: The mean age of the patients with stroke was 67.07 (standard deviation [SD] = 11.2) years; males comprising two-thirds of the study sample (67% [n = 77]). The proxy-rated Sinhala version of the SAQOL-39g showed excellent internal consistency ($\alpha = 0.98$ [overall score]), 0.97, 0.96, and 0.95 for physical, communication, and psychosocial domains, respectively. The intraclass correlation coefficient (ICC) was 0.92 for overall, and 0.93, 0.92, and 0.91 for physical, communication, and psychosocial domains, respectively. Factor analysis extracted 3 factors with 72.4% of the variance.

CONCLUSIONS: Proxy-rated Sinhala version of the SAQOL-39g is a psychometrically sound, reliable, and valid tool to assess the post-stroke quality of life of Sinhala-speaking patients with stroke and aphasia.

KEYWORDS: Stroke, health-related quality of life, psychometric properties, SAQOL-39g scale

Introduction

Stroke is a non-communicable disease (NCD) that can greatly affect the quality of life (QOL). Stroke has become a burden especially for the developing countries in the world with the current epidemiological transition.[1,2] The disabilities and consequences of a stroke can directly affect the social and psychological well-being of the affected individuals and their loved ones.[3,4] Aphasia is one of the main language disorders that occurs as a result of a stroke.[5,6] The prevalence of aphasia is 21% to 38% in the acute stage.[7] The aphasia is an acquired neurogenic disorder of language that mainly affects the verbal expression and the comprehension ability of the patient.[8]

Self-perception of life-related expectations according to one's own value system is considered to be QOL.[9] "Health-related quality of life (HRQOL) reflects the impact of a health state on a person's ability to lead a fulfilling life."[10] The HRQOL assessment is particularly important when weighing rehabilitation interventions for patients with long-term disabilities.[11]

Prior studies used generic scales, such as the 360-item short-form survey (SF-36), to assess the QOL of patients with stroke, rather than using disease-specific tools. Unfortunately, the universal tools do not address the effects of potential dysfunctions of stroke (eg, extremity function, language impairment). The Stroke-Specific Quality of Life (SS-QOL) scale and the Stroke Impact Scale (SIS) are both metrics specifically designed to assess the QOL of patients with stroke.[12,13] However, these scales do not address the QOL of all patients with stroke; as people with aphasia are unlikely to be able to complete these tests, they are often excluded from the validation of these tools and the studies that employ them. The Assessment for Living With Aphasia (ALA) and the Quality of Life Questionnaire for Aphasics (QLQA) are 2 recently developed surveys specifically tailored to patients with aphasia, but these scales too fail to represent the entire population of patients with stroke.[14,15] The Stroke and Aphasia Quality of Life Scale–39 (SAQOL-39) is widely used to determine the HRQOL of patients with aphasia.[12,16] The SAQOL-39g (generic version) was introduced by Hilari et al[17] and carries the advantage of assessing the post-stroke HRQOL of patients with and without aphasia. The SAQOL-39g is an

interviewer-administered questionnaire that measures the HRQOL of people with chronic aphasia. A review of the different validated versions of the SAQOL-39 has established its high reliability and acceptability.[18]

The SAQOL-39g reflects the physical, communication, and psychosocial domains of the HRQOL of patients with stroke. There are 39 specific items that cover self-care ability, mobility, work, upper extremity function, language ability, thinking, personality and mood, and familial and social roles. The SAQOL-39 was adopted and developed based on the SS-QOL scale. The initial version of the SAQOL had 53 items and was reduced to 39 items in the validation process.[16] The SAQOL-39 has a 5-grade scoring system in which higher QOL is indicated with higher scores for the scale. This assessment tool includes a self-reported and proxy-reported version with the advantage of including patients with serious aphasia also.

The SAQOL-39 has been cross-culturally adapted and validated into many languages, including 3 Indian languages: Kannada,[19] Hindi,[20] and Malayalam.[21] It has also been validated into 6 European languages, including Greek, Italian, Turkish, Dutch, Portuguese, and Spanish.[11,22-26] The SAQOL-39 has been validated into a handful of other Asian languages (eg, Chinese, Japanese).[27,28] The generic SAQOL-39 has been translated into English,[17] Mandarin,[29] Greek,[30] and Chinese[31] languages.

To the best of our knowledge, there is no disease-specific tool to determine the QOL of Sinhala-speaking patients with stroke. Previously, Sri Lankan studies used generic QOL scales to assess the QOL of patients with stroke. Patients with severe aphasia have been excluded from these studies as they are generally unable to complete self-reported questionnaires. Thus, it is vital to develop and validate a tool that is stroke-specific in addition to being able to assess the HRQOL of patients with severe aphasia. Furthermore, a comprehensive assessment tool will enable the analysis of rehabilitation intervention outcomes. Validation and cultural adaptation of assessment scales in different languages and different nations enables comparing the QOL of patients with stroke and aphasia across cultures.[20] Sinhala is the main language of Sinhalese ethnic group which is about 80% of people can comprehend. We hypothesize that the proxy-rated version of SAQOL-39g is a psychometrically sound test which is suitable to assess the HRQOL of patients with stroke. Therefore, the purpose of this study was to culturally adapt and validate the proxy-rated Sinhala version of the SAQOL-39g.

Methods

Study design

Cross-cultural adaptation and validation guidelines by Beaton et al,[32] were followed to validate the SAQOL-39g.

Study setting

The study was conducted at the medical and neurology clinics of the Teaching Hospital, Karapitiya, Galle, Sri Lanka. It is the largest tertiary care center in the Southern Province and the third largest tertiary care center in Sri Lanka with facilities dedicated to acute stroke care.

Study sample and sample size

Every consecutive patient (n = 136) admitted to the hospital's medical and neurology departments with a stroke from January to April 2016 was recruited to participate in the study. A total of 115 subjects fulfilled the inclusion criteria and were selected for the study. Patients experiencing their first-ever stroke, aged between 18 and 80 years, who were conscious, and capable of comprehending Sinhala before the stroke were eligible for inclusion. Patients with a brain lesion other than the stroke, a previous history of stroke, behavioral or memory problems, major psychiatric illnesses, or any other neurological disorder; patients with chronic alcohol or narcotic abuse, who are on medication that can affect cognition; and subjects with mental or learning disabilities were excluded from the study. The proxy, who answered the questionnaire on behalf of the patient, should be an immediate family member, caregiver, or a close friend of the patient. They should also capable of comprehending Sinhala.

Ethical considerations

Ethical approval for this study was obtained from the Ethics Review Committee, Faculty of Medicine, University of Ruhuna (ref. 26.05.2015:3.15). Written informed consent was obtained from every participant prior to data collection, including those who participated for the pretest of the scale.

Patients were first screened for aphasia during the acute stage (ie, within the first week of stroke onset) using the Sinhala version of the Mississippi Aphasia Screening Test (MAST).[33] The recruitment of the patients for the study is shown in Figure 1.

Phase 1: cultural adaptation

According to the guidelines described by Beaton et al,[32] there are 5 stages involved in the process of cultural adaptation. In the first stage of adaptation, the SAQOL-39g was translated into Sinhala independently by 2 bilingual individuals, which resulted in 2 translations (T-1 and T-2), and the item content, response options, and instructions were translated in this fashion. With help from a third bilingual person familiar with the original SAQOL-39g, a single translation (T-12) was generated from the 2 independent ones. For the third stage, a back translation (Sinhala translated into English) was
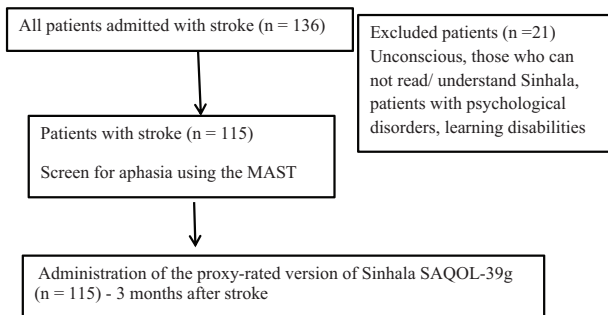
Figure 1. Recruitment of the patients for the study. MAST indicates Mississippi Aphasia Screening Test; SAQOL-39g, Stroke and Aphasia Quality of Life Generic Scale−39.

performed by 2 bilingual persons who were completely blind to the original version. In the fourth stage, the 2 back translations (BT-1 and BT-2) were shared with a panel of experts, which included a consulting neurologist, an experienced speech and language pathologist, and a linguistics expert. All of the translated and original versions were evaluated, and necessary modifications were done in the questionnaire according to the consensus among the panel of experts. The semantic, experiential, and conceptual equivalence of the original English and the new Sinhala version were reviewed during this stage. All of the members of the panel accepted all of the items on the translated version except for 2. Changes were made to the self-care (SC1) and upper extremity function (UE2) items.

The pre-final proxy-rated Sinhala version of the SAQOL-39g was pretested with the participation of an immediate family member or a caregiver of 10 patients with stroke to ensure the understandability and acceptability of the questions. After 3 months of onset of stroke (before 4 months), patients underwent an assessment of their HRQOL using the translated version of the SAQOL-39g. A nominated proxy (an immediate family member or a close friend) was invited to participate in the study on behalf of the patient. The aforementioned nominated proxy responded to the questions of the translated, culturally adapted, proxy-rated version of the SAQOL-39g. The scale was administered by the principal investigator and the proxies answered the questions.

Phase 2: preliminary psychometric validation of the proxy-rated version

Acceptability and reliability. The acceptability of the Sinhala version of the SAQOL-39g was assessed by minimal missing data, floor or ceiling effects, and skewed items. The internal consistency was assessed using Cronbach's alpha (α) and item-total correlations (ITCs). The test-retest reliability was determined by calculating the intraclass correlation coefficient (ICC). Two-way mixed effect analysis of variance (ANOVA) model was used for ICC.

Validity. A panel of experts, including an experienced speech and language therapist, a neurologist, and a linguistics expert, was asked to assess the content validity of the items on the Sinhala version of the SAQOL-39g. Principal axis factors (PAFs) and correlations between the subdomains and the total scores were used to assess the construct validity.

Data analysis and criteria for psychometric evaluation

Data were analyzed using the Statistical Package of Social Sciences (SPSS), version 20. We followed the criteria described by Hilari et al[16] to evaluate psychometric properties. According to the criteria, for acceptability, missing data should be <10%, floor or ceiling effects should be <80%, and skewness should range between +1 and −1. For internal consistency, Cronbach's α should be ⩾0.70 and ITC should be ⩾0.30. Moreover, the accepted criteria for test-retest reliability should be ICC ⩾ 0.75. The Kaiser-Meyer-Olkin (KMO) measure verified the sampling adequacy for the analysis, KMO = 0.92. Bartlett's test of sphericity was significant ($P<.001$). The factor analysis was conducted on 39 items using the varimax rotation. The PAF analysis should provide a conceptually clear model. Items should load ⩾0.4 and should not cross-load (if items load on ⩾2 factors with values ⩾0.4 with a difference <0.2 between them), and it should contain at least 3 items per factor. There should be moderate correlations between the subdomains and total scores (0.30-0.80).[16] A *P* value <.05 was taken as statistically significant.

Results

Sociodemographic and clinical characteristics of the participants

The mean age of the participants with stroke (n = 115) was 67.07 (range: 33-80 years; standard deviation [SD] = ±11.2). Nearly two-thirds of the participants were males (67%, n = 77). Out of 115 patients, 50.4% (n = 58) studied up to ordinary level and 54.8% (n = 63) were married. Of all patients, 80% (n = 92) had ischemic strokes, while rest (20%, n = 23) had hemorrhagic strokes. The percentage of aphasia subsequent to stroke was 38.3% (n = 44). The hypertension was the commonest NCD among study participants (47%, n = 54), and the percentages of diabetes mellitus and dyslipidemia were 30.4% (n = 35) and 33% (n = 38), respectively. Sociodemographic characteristics of the participants are shown in Table 1.

Acceptability. The acceptability of the Sinhala version of the SAQOL-39g was easily evidenced by the missing data (4.8% of total data; contributed by 3 items: M8-1.6%; W2-1.6%; T5-1.6%) and there were no skewed items. Six items (15.4%) showed floor effects, while 14 items (35.9%) exhibited ceiling effects.

Table 1. Demographic characteristics of the patients (n = 115).

CLINICAL CHARACTERISTICS	CATEGORY	N	%
Age	30-50 years	14	12.2
	51-60 years	14	12.2
	61-70 years	35	30.4
	71-80 years	52	45.2
Gender	Male	77	67
	Female	38	33
Level of education	Primary	34	29.6
	Up to ordinary level	58	50.4
	Up to advanced level	13	11.3
	Diploma/degree	10	8.7
Marital status	Married	63	54.8
	Unmarried	33	28.7
	Widowed/separated	19	16.5
Type of stroke	Ischemic	92	80
	Hemorrhagic	23	20
Aphasia	Yes	44	38.3
	No	71	61.7
Non-communicable diseases	Hypertension	54	47
	Diabetes mellitus	35	30.4
	Dyslipidemia	38	33

Reliability. The Sinhala version of the SAQOL-39g displayed excellent internal consistency (Cronbach's α = 0.98). Furthermore, the items of each domain had high Cronbach's α value (physical: 0.97; communication: 0.96; psychosocial: 0.95). The ITCs ranged from 0.58 to 0.84 (overall) and 0.75 to 0.87 (physical), 0.71 to 0.92 (communication), and 0.60 to 0.85 (psychosocial) domains. The test-retest reliability of the Sinhala SAQOL-39g was good. The ICC was 0.92 overall, and 0.93, 0.92, and 0.91 for the physical, communication, and psychosocial domains, respectively.

Validity. The content validity of the Sinhala version of the SAQOL-39g was assessed with the participation of a panel of expertise, including a neurologist, speech and language therapist, and a linguistics expert. Factors were extracted with 72.4% of the variance. Items factored into 3 components as physical, communication, and psychosocial domains. The factor structure of the Sinhala SAQOL-39g is shown in Table 2. Correlations between the subdomains and total scores were acceptable (Table 3). A summary of psychometric properties of the current validation and comparison with the initial English validation of the SAQOL-39g are shown in Table 4.

Discussion

The purpose of this study was to validate the proxy-rated version of the Sinhala SAQOL-39g cross-culturally and to evaluate the psychometric properties. The scale was translated (forward-backward translation) and the psychometric properties were evaluated. The proxy-rated version of the Sinhala SAQOL-39g demonstrated good acceptability, internal consistency, excellent test-retest reliability, and validity. The post-stroke HRQOL of both patients with and without aphasia can be compared using the generic scale of SAQOL-39. Sinhala is the language of the Sinhalese ethnic group, which constitutes 75% of the total population of Sri Lanka. To the best of our knowledge, no studies have investigated stroke in the Southern Province, and data on the prevalence of stroke-induced aphasia in Sri Lanka are limited.

The demographic characteristics of our study sample are in line with the population used for the initial validation of the SAQOL-39g. In a previous study conducted to evaluate the psychometric properties of the generic version of the SAQOL-39, the mean age of the participants was 69.7 years and 37% of them had aphasia.[17] We evaluated the HRQOL of patients with stroke using the proxy-rated version of this scale, to

Table 2. Factor structure of the Sinhala SAQOL-39g.

FACTOR	SAQOL-39 ITEM	LOADINGS
Physical	SC1-Trouble with preparing food	.69
	SC4-Trouble with getting dressed	.55
	SC5-Trouble with taking a bath/shower	.67
	M1-Trouble with walking	.76
	M4-Trouble with keeping balance	.58
	M6-Trouble with stairs	.84
	M7-Trouble with walking with no rest	.74
	M8-Trouble with standing	.65
	M9-Trouble with getting out of the chair	.65
	W1-Trouble with doing daily work	.82
	W2-Trouble with finishing jobs	.57
	UE1-Trouble with writing	.63
	UE2-Trouble with brushing teeth	.67
	UE4-Trouble with doing buttons	.57
	UE5-Trouble with doing a zip	.52
	UE6-Trouble with opening a jar	.71
Communication	L2-Trouble with speaking	.87
	L3-Trouble with using the phone	.87
	L5-Trouble with being understood	.84
	L6-Trouble with finding words	.86
	L7-Trouble with repetition	.68
	FR9-Language problems effect on family life	.61
	SR8-Language problems effect on social life	.87
Psychosocial	T4-Having to write things down to remember	.63
	T5-Finding it hard to make decisions	.55
	P1-Feeling irritable	.78
	P3-Feeling that your personality has changed	.54
	MD2-Feeling discouraged	.57
	MD3-Having no interest in people	.60
	MD6-Feeling withdrawn	.65
	MD7-Having little confidence	.84
	FR7-Feeling a burden to family	.63
	E2-Feeling tired often	.55
	E3-Having to stop and rest often	.70
	E4-Feeling too tired to do what you want	.74
	SR1-Going out less	.62
	SR4-Doing hobbies less	.63
	SR5-Seeing friends less	.54
	SR7-Physical problems effect on social life	.64

Abbreviations: E, energy; FR, family relationships; L, language; MD, mood; P, personality; SAQOL-39g, Stroke and Aphasia Quality of Life Generic Scale–39, SC, self-care; SR, social relationships; T, thinking; UE, upper extremity functions; W, work.

Table 3. Inter-domain correlations within the SAQOL-39g.

	PHYSICAL	COMMUNICATION	PSYCHOSOCIAL	OVERALL
Physical	1	0.19*	0.21*	0.27**
Communication		1	0.80**	0.84**
Psychosocial			1	0.94**
Overall				1

Abbreviation: SAQOL-39g, Stroke and Aphasia Quality of Life Generic Scale–39.
*The Pearson correlation is significant at the .05 level (2-tailed). **The Pearson correlation is significant at the .01 level (2-tailed).

Table 4. Acceptability, reliability, and internal validity of the original and Sinhala versions of the SAQOL-39g.

PROPERTIES	CRITERIA FOR ACCEPTABILITY	RESULTS	
		SAQOL-39G ORIGINAL VERSION (N=71)	SAQOL-39G SINHALA VERSION (N=115)
Scale range		1.00-5.00	1.00-5.00
Mean (SD)		3.97 (0.86)	3.40 (0.95)
Acceptability			
Missing	<10%	0	4.8%
Floor	<80%	0	6
Ceiling	<80%	19	14
Skewness (>±1)	<25% of items	25 items (64.1%)	0
Internal consistency	Cronbach's alpha >0.7	Overall=0.96	Overall=0.98
Cronbach's alpha		Physical=0.94	Physical=0.97
Overall score		Psychosocial=0.94	Psychosocial=0.96
Domains		Communication=0.98	Communication=0.95
ITCs	ITC≥0.30	Overall=0.37-0.79	Overall=0.58-0.84
		Physical=0.42-0.85	Physical=0.75-0.87
		Psychosocial=0.56-0.81	Psychosocial=0.60-0.85
		Communication=0.85-0.98	Communication=0.71-0.92
Test-retest reliability		n=24	n=75
Overall score	ICC>0.75	Overall=0.99	Overall=0.97
Domains		Physical=0.99	Physical=0.93
		Psychosocial=0.98	Psychosocial=0.91
		Communication=0.99	Communication=0.92
Construct validity			
Factor analysis		3 factors	3 factors
Internal validity Intercorrelations between overall score and domains (*r*)	Moderate correlations expected (0.30-0.80)	Physical=0.74*	Physical=0.27*
		Psychosocial=0.95*	Psychosocial=0.94*
		Communication=0.61*	Communication=0.84*

Abbreviations: ICC, intraclass correlation coefficient; ITCs, item-total correlations; SAQOL-39g, Stroke and Aphasia Quality of Life Generic Scale–39; SD, standard deviation.
*The Pearson correlation is significant at the .05 level (2-tailed).

include all patients regardless of aphasia severity and to minimize raters' bias. In the Chinese version of the SAQOL-39g, 2 versions were used as self-reported and proxy-reported scales, but there were no statistically significant differences between the patients with aphasia and their proxies.[31]

During the cultural adaptation process, according to the suggestions of the panel of experts, 2 items (SC1 and UE2) were changed. As food preparation is mostly done by females in Sri Lanka, male subjects may consider this question to be inappropriate for them. Therefore, SC1 was changed to "preparing food/having food?" In its initial form, UE2 was "trouble with putting on socks," but wearing socks is not common among the citizens of Sri Lanka especially those with lower socioeconomic status. Therefore, this item was replaced with "brushing teeth" as another day-to-day activity that uses upper extremities.

The acceptability of the proxy-rated version of the Sinhala SAQOL-39g is acceptable according to the acceptability criteria established by Hilari et al.[16]

The proxy-rated version of the Sinhala SAQOL-39g demonstrated excellent internal consistency (Cronbach's $\alpha = 0.98$), and these results are similar to previous versions of the SAQOL-39g. Recently, a Chinese version of the SAQOL-39g was shown to have good internal consistency. For the self-reported and proxy-reported scales, the Cronbach's α values were 0.95 and 9.94, respectively.[31] Cronbach's α was 0.95 and 0.96 in the initial English[17] and Greek versions.[30] In the Singaporean study, there was good internal consistency for both the English and Mandarin versions ($\alpha = 0.96/0.97$).[29] The test-retest reliability was also good in the present study (ICC = 0.92) and in line with previous studies. In the Chinese version, ICC = 0.897 for the self-reported scale and 0.966 for the proxy-reported scale.[31] The ICC was 0.96 in both the English and Greek versions of the SAQOL-39g.[17,30] The Singaporean version also demonstrated good test-retest reliability in both its English and Mandarin forms (ICC = 0.99/0.98).[29] Therefore, the Sinhala version of the SAQOL-39g has a good reliability and internal consistency, and in line with proper acceptability criteria.

We used PAF analysis to demonstrate the construct validity of the scale. A conceptually clear model was identified in the present study comprised of 3 factors: physical, communication, and psychosocial, which is similar to the initial English version. All items were more than 0.4 for factor loadings, and it is acceptable according to the factor analysis criteria put forth by Hilari et al.[16] The initial English version[17] and the Greek[30] and Chinese[31] adaptations of the SAQOL-39g illuminated 3 conceptually distinct factors: physical, psychosocial, and communication. In the Greek version, the psychosocial domain explained 48% of the variance. In addition, authors pointed out there is more than one underlying construct in the psychosocial domain, but a conceptually clear model was not identified through further analysis.[30] Therefore, our findings are also in line with previous validations of the generic version of SAQOL-39.

Limitations

In our study, we used the proxy-rated version of the SAQOL-39g. As we know, some questions related to the HRQOL are highly subjective and there may be an influence on the results than assessing the actual perception of the QOL of the patients. The severity of aphasia limits self-reporting ability of the patients and they may have worse QOL compared with other patients with stroke. In previous Sri Lankan studies concerning post-stroke QOL, no evidence exists on patients with aphasia. As it is vital to assess the QOL of those with severe aphasia, we prioritized validating the proxy-reported version. Although there are disagreements about using proxy versions, according to a recent Chinese study, there was no statistically significant difference between proxy-reported and self-reported measures.[31] The sample size is one of the limitations of our study. Moreover, as there is a lack of culturally adopted scales, we could not assess the convergent validity of the scale.

Recommendations

Future studies should be conducted to assess the psychometric properties of the self-reported version of the Sinhala SAQOL-39g.

Conclusions

The proxy-rated version of the Sinhala SAQOL-39g is a psychometrically valid and reliable test to assess the post-stroke HRQOL of patients with and without aphasia. The scale demonstrated good acceptability, internal consistency, test-retest reliability, and construct validity. Furthermore, it facilitates comparisons between cross-cultural and cross-linguistic QOL data from people with stroke-induced aphasia across different centers.

Clinical message

The clinical outcomes of the patients with aphasia and stroke in Sri Lankan context can be measured using the proxy-rated version of the SAQOL-39g. This scale provides a basis for future studies to evaluate the HRQOL of patients with stroke, including those with aphasia, by filling the gap created by the lack of standardized disease-specific measures. The data concerning HRQOL provide a basis for the design and evaluation of rehabilitation interventions that will inevitably contribute to their improvement.

Author Contributions

PNK contributed to data collection and interpretation and writing the paper. KDP contributed to interpreting data and critically revised the paper. DCH analyzed and interpreted

data and revised the paper. RDAD was involved in the transla-tion of the scale and writing the paper.

Ethical Approval and Consent to Participate

This study was approved by the Ethics Review Committee, Faculty of Medicine, University of Ruhuna (ref. 26.05.2015: 3.15).

Written Informed Consent

Written informed consent was provided by the patient or their next of kin patient prior to their participation in the study.

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