

## ORIGINAL ARTICLE

# Linguistic and Content Validation of the Stroke Impact Scale (SIS) 3.0 in Three Languages

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## ABSTRACT

**Introduction:** A stroke can have devastating consequences and may reduce the Quality of Life (QoL) of stroke survivors. Specific QoL measurement is therefore needed to appreciate and quantify the impact of this condition. The objective of the study is to culturally adapt, translate and validate the Bahasa Melayu, Mandarin and Tamil versions of the Stroke Impact Scale (SIS) 3.0 for its application in clinical practice and stroke research in Malaysia. **Methods:** A total of nine translators translated the SIS 3.0 and five professional experts carried out the linguistic validation of the SIS 3.0 in accordance with the Mapi Research Institute's linguistic validation guideline. The steps for linguistic validation included forward translation, synthesis, backward translation, clinicians' review, and cognitive debriefing. Ten to thirteen healthcare practitioners rated the translated versions of SIS 3.0 using the Content Validity Index (CVI) and Content Validity Ratio (CVR). **Results:** During the translation processes, concerns were expressed about various grammatical and semantic issues, such as the appropriateness of some phrases used for the Malaysian demographic. The Scale-CVI average was 0.91 and 0.95 for relevance and clarity respectively which indicated excellent content validity. The CVR values ranged from 0.40 to 1.00. **Conclusion:** The Bahasa Melayu, Mandarin and Tamil versions of SIS 3.0 was well developed. The translated versions of SIS 3.0 could be adopted in clinical, community and educational settings. Nevertheless, further in-depth psychometric testing including construct validity and reliability on a larger sample among the multi-ethnic Malaysians stroke survivors is advised.

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## INTRODUCTION

In 2014, Malaysia reported that stroke was the top three cause of total disability-adjusted life years, accounting for 7.9% (1). Even worst, the number of stroke incidence in Malaysia has escalated over the years (2). One year post stroke, 30% of survivors reported substantial disabilities (3). The consequence of stroke has affected the individual to lose a significant amount of functionality and participation in daily activities (4). The impairment in functioning and participation also influences the Quality of Life (QoL) of these stroke survivors.

In clinical trials, many standard and disease-specific evaluation tools have been created, but their utility in investigating the impact of stroke and its treatments are limited (5). Among the instruments used for stroke, Tse et al. (6) suggested three instruments—Stroke Impact Scale (SIS), Assessment of Life Habits (LIFE-H), and Activity Card Sort as these three were most frequently used, have established psychometric properties, and has the widest coverage of International Classification of Functioning, Disability and Health's Activities and Participations domains. Among these, the SIS received a growing demand for its use across cultures as in different countries, cultural adaption of QoL instruments using standard guidelines is becoming increasingly relevant (7-9). Currently in Malaysia, only a few QoL instruments were found to be used among the stroke population (10-14), however, not all studies provided information on its

available language and translation.

To the extent of our knowledge, the SIS 3.0 has not been translated into Bahasa Melayu, Mandarin or Tamil languages, although it has been found to be used in Malaysia (15). Malaysia has significant composition of three ethnicities which are Malay, Chinese and Indian (16). Bahasa Melayu is the official national language, which is also the native language for the Malay community, while Mandarin and Tamil are the dominant spoken language for the Chinese and Indian ethnicity respectively. As many of the stroke survivors are among the older population, many of the elderly from each ethnic group has difficulty to understand English, especially those who are with low education or from a lower income group and reside in the rural area. It should be noted that some non-Malay elderly also have difficulty in Bahasa Melayu comprehension (17, 18). This has hampered effective evaluations and may result in sub-par service. Due to the fact that the SIS 3.0 was initially created in English, it was believed necessary to conduct a proper language validation of the instrument before it could be used by a larger population in Malaysia. This paper describes the process of translation, transcultural adaptation, and linguistic validation of the English version of the SIS 3.0 into Bahasa Melayu, Mandarin and Tamil languages for future use in clinical practice and research in Malaysia.

## MATERIALS AND METHODS

Approval of ethics was obtained from the Universiti Putra Malaysia Ethic Committee for Research involving Human Subject (JKEUPM-2020-247). Permission was also obtained for the cross-cultural adaptation and content validation of the SIS 3.0 into Bahasa Melayu, Mandarin and Tamil from the developers and the copyright owners (19) via the Mapi Research Trust.

### Instrument

The Stroke Impact Scale (SIS) was created comprehensively to evaluate stroke survivors' health status (19, 20). The SIS is a self-administered instrument that combines significant functional characteristics and health related QoL into a single self-report questionnaire (21). The scale was created at the Landon Centre on Aging, University of Kansas and was initially released as version 2.0 (19). Currently there are four versions of the SIS which are SIS 2.0, SIS 3.0, SF-SIS (22) and SIS-16 (23). The current SIS 3.0 (20) is a revised version of the original SIS (19), widely accepted, and with good validity and reliability established (7, 9, 24, 25). The scale has 59 items evaluating eight domains, including personal and instrumental activities of daily living, strength, hand function, mobility, memory and thinking, emotions, participation, and communication, with one item evaluating perceived global stroke recovery (26). Each item is rated using a 5-point Likert scale from 1 to 5 and domain score are calculated

using the following equation:  $[(\text{Mean item score} - 1) / 5 - 1] \times 100$ . Each domain has a score ranging from 0 to 100, and higher scores indicate a better outcome (25). Items for mobility, memory, communication, and personal/instrumental ADL are scored in terms of strength while hand function are scored according to difficulty. However, participation and emotion domains are scored according to their frequency. Combining four of the subscales (hand function, mobility, strength, and personal/instrumental ADL) produces a composite physical domain (21). To assess overall stroke recovery, respondents rate their recovery percentage on a Visual Analog Scale of 0 to 100, with 0 indicating no recovery and 100 indicating full recovery (21). Currently, the translated versions of the SIS are available in Korean (27), Brazilian (25), Portuguese (28), Hausa (8), Luganda (9) and Gujarati (29).

### Translation and cross-cultural adaptations

The goal of the translation was to create a standard version of the Stroke Impact Scale 3.0 in three languages with equivalence in concept, semantics, and operation to the primary English edition (30). A guideline from Mapi Research Trust Institute which included five stages namely forward-translation, synthesis, backward-translation, revision with experts and cognitive debriefing was applied to establish the translated questionnaire in terms of its cultural adaptation while maintaining its original linguistics (31).

#### *Forward translation and synthesis*

A total of six translators were involved during this stage. For every language version, the two translators were locals of the relevant languages and were English proficient. The first translator's background was in health, while the other was a translator was a non-health professional (30). They worked separately without interfering with one another's work. The two versions were then harmonized by the researchers as accurate as possible to be more reflective of the original content and language appropriate. A single reconciled version of the three languages were then produced.

#### *Backward translation*

A total of three qualified translators who were native of the respective languages, English proficient, and had no experience with the questionnaire performed the backward translation into English (30). Via a discussion, a multidisciplinary team compared the backward translated version to the original SIS 3.0, resulting in a second reconciled version in the corresponding three languages. Similarly, all disparities in translation and linguistic concerns discovered during this stage were addressed and rectified.

#### *Clinicians' review and cognitive debriefing*

The multidisciplinary team discussion was held via a recorded teleconference. One physiotherapist, a speech therapist, two occupational therapists and one

rehabilitation physician discussed to obtain the necessary output to be included into the third revised version of SIS 3.0. The team had representative from each ethnic language (Bahasa Melayu, Mandarin and Tamil) in the study. As Bahasa Melayu is the official national language of Malaysia, the Bahasa Melayu version was adopted as a guide for the other two languages (30). Hence, any discrepancies between the other two languages were reviewed and harmonized in tandem with the Bahasa Melayu version. Face-to-face interviews for the cognitive debriefing stage was conducted with eight stroke respondents (age ranged from 38 to 71 years, five Malay and one Chinese and two Indian ethnicities respectively) who took approximately 20-25 minutes to fill up the questionnaire. This pilot session was conducted to obtain feedback on the instrument from respondents. Based on the reviews from clinicians and respondents, the three language versions were finalized.

### Content validation

Healthcare practitioners were recruited as the expert panel and were given the Bahasa Melayu, Mandarin or Tamil versions of the SIS 3.0 with a Content Validity Index scale to assess its content validity. The panel needed to rate the relevance and clarity of each item using a 4-point scale (1–not relevant/clear, 2–somewhat relevant/clear, 3–quite relevant/clear, and 4–highly/very relevant/clear) (32). The necessity of items was also recorded for calculation of Content Validity Ratio (CVR) in 3-point Likert rating scale: 1, not necessary; 2, useful but not necessary; and 3, essential (33). The researchers calculated the proportion of risk factor agreements to the overall number of reviews. Low-agreement items were reviewed, revised, or eliminated.

### Data analysis

The CVR was computed for each item in the instrument as follows (33) (with  $n_e$  as the number of experts indicating a measurement item is essential and  $N$  as the total number of experts that answer to that item):

$$CVR = \frac{[n_e - 2 (N / 2)]}{(N / 2)}$$

The Content Validity Index (CVI) (32) can be measured using the Item-CVI (I-CVI). I-CVI is determined by dividing the number of experts who rated each item as “very relevant” or “extremely relevant” by the total number of experts. Values range from 0 to 1; where I-CVI 0.80 and above indicates the item is relevant, between 0.70 and 0.79 indicates the item needs to be revised, and any item valued below 0.70 may be excluded (32). Next, the Scale-CVI Average (S-CVIAve) calculates the overall content validity by taking the mean value; the I-CVI is summed and divided by the number of items. An S-CVIAve  $\geq 0.90$  indicates good content validity (34).

In addition, a Modified Kappa Index was calculated to estimate the I-CVI (35, 36). The modified Kappa ( $k$ ) is a measure of consensus between experts that indicates,

beyond chance, that the item is relevant, clear, or has another feature of interest (35). To calculate the modified kappa, the Probability of Chance agreement ( $P_c$ ) was first calculated for each item by following formula:  $P_c = [N! / A! (N - A)!] * 5^N$ , with  $N$  = number of experts in a panel and  $A$  = number of experts who agree that the item is relevant. Then, the values were computed in the following formula:  $k = (I-CVI - P_c) / (1 - P_c)$  (37). Fleiss's (38) and Cicchetti and Sparrow's (39) standards were applied to interpret  $k$ .

## RESULTS

### Linguistic validation

A few alternations were made based on the suggestions from the expert panel and stroke survivors. For item “remember the day of the week”, confusion arose whether the respondent was required to remember all the days in one week or remember what day was today (when asked the question). After discussion, it was decided that the respondent must be able to remember all the days in a week. For item “enjoy things as much as ever”, the word “things” was considered vague and there was consensus to translate the word ‘thing’ into ‘life or events that happen in life’. Meanwhile, for item “cut your food with a knife and fork”, Malaysians rarely use utensils and usually eat by using their hands instead, or using cultural utensils (i.e., chopsticks). Thus, the item was changed to a general statement of “feeds self” (including using utensils). As for item “walk one block”, Malaysians are not familiar with the imperial system and use the metric system in measurement. Hence, the approximate distance equivalent to one block (i.e., 100 meters) was included. For item “climb several flights of stairs”, the word “flight” is also not commonly used among Malaysian when describing height. One flight of stairs is equivalent to ten steps. Thus, the item was revised to include the number of steps which resulted in the inclusion of the phrase to “more than 10 steps”. Lastly, for item “your social activities”, the word “social” was very general and stroke survivors needed examples when asked the question. Hence, examples of common social events were included in the item such as “attending a wedding, party or a gathering”.

### Content validity

A total of ten to thirteen healthcare practitioners participated in rating the translated Bahasa Melayu, Mandarin or Tamil version of SIS 3.0 by using the CVI scale for its relevance and clarity and the CVR for necessity of the questions. The practitioners consisted of three medical doctors, four occupational therapists, three physiotherapists, two speech therapists and one nurse with a mean age of 36.46 ( $\pm 3.02$ ) years (ranged from 30-40 years old) and had work experience ranging from 5 to 15 years.

The majority of the SIS 3.0 items achieved excellent content validity in terms of relevance and clarity.

Seven items had good content validity (items: blame self for mistakes, call another person on the telephone, ability to help others, tie a shoelace, feeds self (using utensils such as spoon, fork, or knife, open a can or jar and pick up a coin). As for clarity, only one item (foot/ankle most effected) had a value of less than 0.80.

For CVR, the majority of items had a value of 0.60 and more except for items- foot/ankle most effected, tie a shoelace, pick up a coin and ability to help others. The results were consistent for both CVI and CVR. Table I reports the content validity of the SIS 3.0. This is parallel with the findings from the clinicians' review for

**Table I: Content Validity of the Stroke Impact Scale in Three Languages**

Item	Relevance (Number of Experts=13)		Clarity (Number of Experts=10)		CVR*** (Number of Ex- perts=10)
	I-CVI**a	k**a	I-CVI**a	k**a	
1. Arm most effected	1.00	1.00	0.80	0.79	1.00
2. Grip of hand most effected	1.00	1.00	0.90	0.90	1.00
3. Leg most effected	1.00	1.00	0.80	0.79	1.00
4. Foot/ankle most effected	0.92	0.92	0.70	0.66	0.40
5. Remember things people just told	1.00	1.00	0.90	0.90	1.00
6. Remember things that happened the day before	1.00	1.00	0.90	0.90	0.80
7. Remember to do things	0.92	0.92	0.80	0.79	1.00
8. Remember days of the week	0.92	0.92	0.80	0.79	0.60
9. Concentrate	0.92	0.92	1.00	1.00	1.00
10. Think quickly	0.92	0.92	0.90	0.90	0.60
11. Solve everyday problems	0.85	0.84	1.00	1.00	1.00
12. Feel sad	0.92	0.92	1.00	1.00	1.00
13. Feel there is nobody close to	0.85	0.84	0.90	0.90	0.80
14. Feel a burden to others	1.00	1.00	1.00	1.00	1.00
15. Feel have nothing to look forward to	1.00	1.00	1.00	1.00	1.00
16. Blame self for mistakes that you made	0.77	0.76	0.90	0.90	1.00
17. Enjoy things as much as ever	0.92	0.92	0.80	0.79	0.80
18. Feel quite nervous	0.92	0.92	0.90	0.90	0.60
19. Feel life is worth living	1.00	1.00	1.00	1.00	1.00
20. Smile and laugh at least once a day	1.00	1.00	0.90	0.90	0.80
21. Say name of someone in front of you	0.92	0.92	0.80	0.79	1.00
22. Understand what is being said in a conversation	0.92	0.92	1.00	1.00	0.80
23. Reply to questions	1.00	1.00	1.00	1.00	1.00
24. Correctly name objects	0.92	0.92	1.00	1.00	1.00
25. Participate in a conversation with a group of people	0.92	0.92	1.00	1.00	0.80
26. Have conversation on the telephone	0.85	0.84	1.00	1.00	1.00
27. Call another person on the telephone	0.69	0.66	1.00	1.00	1.00
28. Feeds self	0.69	0.66	1.00	1.00	1.00
29. Dress top part of body	0.92	0.92	1.00	1.00	1.00
30. Bathe self	0.92	0.92	1.00	1.00	1.00
31. Clip own toenails	0.92	0.92	1.00	1.00	0.60
32. Get to the toilet on time	0.92	0.92	1.00	1.00	1.00
33. Control bladder	0.92	0.92	0.90	0.90	1.00
34. Control bowels	0.92	0.92	1.00	1.00	1.00
35. Do light household task	0.85	0.84	1.00	1.00	1.00
36. Go shopping	0.85	0.84	1.00	1.00	0.60
37. Do heavy household chores	0.92	0.92	1.00	1.00	0.80
38. Stay sitting without losing balance	1.00	1.00	0.90	0.90	1.00
39. Stay standing without losing balance	1.00	1.00	0.90	0.90	1.00
40. Walk without losing balance	1.00	1.00	0.90	0.90	1.00
41. Move from a bed to a chair	1.00	1.00	1.00	1.00	1.00
42. Walk one block	0.85	0.84	1.00	1.00	1.00
43. Walk fast	0.85	0.84	1.00	1.00	0.60
44. Climb one flight of stairs	0.92	0.92	1.00	1.00	0.80
45. Climb several flights of stairs	0.92	0.92	1.00	1.00	0.60

**Table 1: Content Validity of the Stroke Impact Scale in Three Languages (continued)**

Item	Relevance (Number of Experts=13)		Clarity (Number of Experts=10)		CVR*** (Number of Ex- perts=10)
	I-CVI**a	k**a	I-CVI**a	k**a	
46. Get in and out of car	0.92	0.92	1.00	1.00	1.00
47. Carry heavy objects	0.92	0.92	1.00	1.00	0.60
48. Turn a doorknob	0.92	0.92	1.00	1.00	1.00
49. Open a can or jar	0.77	0.76	1.00	1.00	0.80
50. Tie a shoelace	0.77	0.76	1.00	1.00	0.40
51. Pick up a coin	0.77	0.76	1.00	1.00	0.40
52. Work	0.92	0.92	1.00	1.00	1.00
53. Social activities	0.92	0.92	1.00	1.00	0.60
54. Quiet recreation	0.85	0.84	1.00	1.00	0.80
55. Active recreation	0.85	0.84	1.00	1.00	1.00
56. Role as a family member	0.92	0.92	0.80	0.79	0.80
57. Participation in spiritual or religious activities	0.92	0.92	1.00	1.00	1.00
58. Ability to control life	0.92	0.92	0.80	0.79	1.00
59. Ability to help others	0.77	0.76	0.90	0.90	0.40
60. Overall stroke recovery	1.00	1.00	1.00	1.00	1.00
Scale-CVI Average		0.91		0.95	-

*\*Item-Content Validity Index, \*\* Modified Kappa, \*\*\*Content Validity Ratio*

*a Evaluation criteria for level of content validity: relationship between I-CVI and k; excellent validity = I-CVI ≥ 0.78 and k > 0.74, good validity I-CVI ≥ 0.60 to < 0.78 and k ≤ 0.74, fair validity I-CVI ≥ 0.40 to < 0.6 and k 0.59) or poor validity I-CVI < 0.4 and k < 0.40.*

the linguistic validation described above. A discussion was made among the researchers and the multi-ethnic multidisciplinary team on the findings and appropriate modifications on every language version. Thus, the first reconciled version considers the changes required before the cognitive debriefing with the stroke respondents.

The stroke respondents who participated in the pilot study did not have problems with comprehending the contents of the translated versions of the SIS 3.0. There was representation of each ethnic group in the stroke samples. However, for the Bahasa Melayu version, they did find some of the scales (e.g., a lot of strength, not difficult at all) were too lengthy in words. Thus, a review of the scale was conducted, and efforts were made to further simplify the words.

## DISCUSSION

In this study, the linguistic and content validity of the SIS 3.0 in assessing quality of life of stroke survivors were evaluated. The cross-cultural adaptation and the content of the translated versions of SIS 3.0 have been established. This approach was discovered to be highly beneficial, time saving and cost-effective. This protocol is beneficial for a study setting that has a multi-ethnic composition to adopt, as having a survey data from native-language questionnaire were found to be more reliable (40). The involvement of the panel of experts in the preliminary translation was crucial in order to make the content simple to read and understand and also to ensure that the cultural and linguistic relevance in the Malaysian context were addressed (41). The difficulty of translation assessment is evident but can be rectified, as similarly found in other linguistic validation studies

conducted in Malaysia (42-44).

With the growing emphasis on evidence-based practice; reliable and valid outcome measures, as well as comprehensive cultural adaptations of standard measures are necessary (27). Using more general, direct and neutral words ensure a clear message to be received to the intended population. For example, a study had established the relationship between patient's self-blame and quality of life. However, clarification of the concept of self-blame was required to determine whether it can be hypothesised as a behavioural and characterological trait (45). A similar issue happened on cultural applicability. For example, the item "cut your food with a knife and fork" is less applicable due to cultural differences (46) and it was evident from the content validity score as well as in the cognitive discussion. Thus, it was settled by replacing the term into a general one. For 'tie a shoelace' item, it becomes less relevant as most stroke survivors are suggested to wear non-shoelaces fitted shoes and due to the culture of Asians to be barefooted at home or wear slippers (47). The item "tie a shoelace" which is meant to assess fine motor skills could be changed to another fine motor activity such as "tie a ribbon".

Expert translations alone are not successful in producing questions that are semantically equivalent to the original English, hence, it is critical to evaluate the notion, cultural significance and implications of words and phrases (27). Although a few of the items had low CVR values, the items were retained as this was a preliminary study that consist of three translated languages. Construct validity and reliability should be examined to finalize the items for the scale. Nevertheless, the majority of the

items achieved excellent content validity.

Given the fact of limited comprehensive stroke recovery outcome measures in evaluating the impact of stroke and stroke interventions (5), the availability and use of SIS 3.0 in Bahasa Melayu, Mandarin, and Tamil will give useful information and improve treatment outcomes for healthcare practitioners and researchers working to improve the quality of life of stroke survivors. It may also be beneficial in giving researchers and professionals an illustration of stroke recovery, as well as in developing more holistic rehabilitation therapies, resource allocation, policy making, and service planning for rehabilitation (8).

## CONCLUSION

This study indicates that the Bahasa Melayu, Mandarin and Tamil versions of SIS 3.0 was successfully developed and had excellent content validity. The translated versions of SIS 3.0 could be adopted in clinical and community settings for the Malaysian stroke population. It is recommended for future studies to examine the construct validity and reliability of the scale.

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