

## Asian Adaptation and Validation of an English Version of the Multiple Sclerosis International Quality of Life Questionnaire (MusiQoL)

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### Abstract

**Introduction:** The Multiple Sclerosis International Quality of Life questionnaire (MusiQoL) is a self-administered, multi-dimensional, patient-based health-related quality of life (HRQoL) instrument. With increasing prevalence of multiple sclerosis (MS) in Asian countries, a valid tool to assess HRQoL in those patients is needed. The aim of this study was to evaluate patient acceptability, content validity and psychometric properties of an Asian version of the English MusiQoL in Singapore, Malaysia and India. **Materials and Methods:** English speaking patients older than 18 years of age with a definite diagnosis of MS were included. The self-administered survey material included the adapted HRQoL questionnaire, a validated generic HRQoL questionnaire: the short-form 36 (SF-36), as well as a checklist of 14 symptoms. We assessed the internal and external validity of the adapted MusiQoL. **Results:** A total of 81 patients with MS were included in the study. The questionnaire was generally well accepted. In the samples from Malaysia and Singapore, all scales exhibited good internal consistency (Cronbach's alpha >0.70). Correlation to SF-36 was generally good, demonstrating high construct validity ( $P < 0.001$ ) in some aspects of the MusiQoL. **Conclusion:** The Asian adaptation of the English version of the MusiQoL in evaluating HRQoL seems to be a valid, reliable tool with adequate patient acceptability and internal consistency.

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### Introduction

Multiple sclerosis (MS) is one of the most common disorders of the central nervous system with a lifetime risk of 1 in 400.<sup>1</sup> In about 75% of MS patients, activities of daily living will become affected at later stages. In up to 15% of patients, the disabilities will become severe within a short time.<sup>1</sup> Therefore, MS has a great impact on health-related quality of life (HRQoL). In order to identify public health needs and to evaluate therapeutic efficacy of new drugs, the assessment of health-related quality of life (HRQoL) is important.

A self-administered, multi-dimensional, patient-based HRQoL instrument, the Multiple Sclerosis International Quality of Life questionnaire (MusiQoL), has been developed and validated.<sup>2</sup> It is available in 14 languages and can be applied internationally.

In Asia, MS is perceived to be much less common than in western countries. However, a recent increase in prevalence

has been observed within the Asian regions.<sup>3,4</sup> Several oral therapies and monoclonal antibodies are showing promising results in MS. They will provide new treatment options not only in terms of drug administration, but also regarding their mechanisms of action. With an increasing number of immune modulating therapies now available in Asia, a valid and valuable tool is needed to comprehensively evaluate treatments as well as to assist in managing the care of MS patients.

The objective of this study was to evaluate patient acceptability, content validity and psychometric properties of an Asian version of the English MusiQoL in Singapore, Malaysia and India.

### Materials and Methods

#### Patients

Patients were recruited from neurological departments of in- and outpatient clinics in Singapore, Malaysia and

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India during 2004 and 2005. Patients had to be older than 18 years of age, be native English speakers, and they had to have a definite diagnosis of MS according to the criteria by Poser<sup>5</sup> and/or MacDonald.<sup>6</sup> The MS had to be diagnosed at least 6 months before study entry. Patients were excluded from the study if they had a diagnosis other than MS, were suffering from dementia, were currently experiencing a severe relapse of their MS, or were unable to complete the questionnaires by themselves.

### *Study Design*

At study entry, the patients were evaluated by an experienced neurologist from each country using the Poser and/or McDonald criteria, the Kurtzke Functional Systems, the Expanded Disability Status Scale (EDSS), the Ambulation Index (AI), the Mini Mental State Examination (MMSE) and a Clinical Global Impression (CGI) of severity (mild, moderate and severe). Additionally, socio-demographic data, clinical history related or unrelated to the MS, and data related to the treatment of MS were collected by the neurologists. Each patient had to sign an informed consent form. Patients were asked to complete a self-administered questionnaire at inclusion (T0), and  $21 \pm 7$  days later (T1). The survey material included the adapted HRQoL questionnaire (MusiQoL), a validated generic HRQoL questionnaire: the short-form 36 (SF-36),<sup>7</sup> as well as a checklist of 14 symptoms. The patients were invited to give open-ended feedback on content clarity and validity of the questionnaire through the following questions: "Please indicate if any questions are unclear for you and why?" and "Are there other important areas of your life related to your health that we did not ask about in this questionnaire?"

### *Details of the Survey Questionnaires*

The Multiple Sclerosis International Quality of Life Questionnaire (MusiQoL) is a disease specific self-administered scale for patients with MS.<sup>2</sup> The clinical version of the original MusiQoL encompasses 74 questions. After adaptation, the Asian version of the MusiQoL was shortened to 31 questions. These questions cover the following 9 domains: activities of daily living (ADL), physical well being (PWB), symptoms (SPT), relations with friends (RFR), relationships with family (RFa), relationships with healthcare system (RHCS), sentimental and sexual life (SSL), coping (COP) and rejection (REJ) using scales similar to those from Likert, but with a score range of 0 to 100. Scores of negatively worded items were reversed so that higher scores indicated a better HRQoL. For each patient, the score of each scale was obtained by computing the mean of the item scores of the scale. If less than 50% of the items were missing, the mean of the non-missing items for a given scale was substituted for the missing items; if more than 50% of the items for a given scale were missing,

the scale was not scored. The MusiQoL global score was computed as the mean of 9 scale scores.

The Short-Form 36 Health Survey (SF-36) is a widely used generic HRQoL instrument.<sup>7</sup> It contains 36 items measuring perceived health in 8 domains, namely, physical functioning (PF), role-physical (RF), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH), with higher scores (range 0–100) reflecting better perceived health.

The symptom checklist comprises 14 symptoms commonly reported by patients with MS, for example 'lack of sensation in touch', 'lack of sensation in position', 'fatigue', 'visual problems', and 'urinary incontinence', among others.

### *Psychometric Property Analysis*

A test of scaling assumption was performed by evaluating (a) item-internal consistency and (b) item-discriminant validity. The item-internal consistency assesses the extent to which one item is related to the other items of its scale; it was measured using item-scale correlation analysis with correction for overlap. A scaling success refers to an item-scale correlation (corrected for overlaps) exceeding 0.40.<sup>8</sup> For item-discriminant validity, scaling success refers to an item correlating higher with the dimensions it is hypothesised to represent than with the other ones (item-scale correlation >0.40) compared to another unrelated scale (item-scale correlation <0.40) in the questionnaire. For both tests, the extent of overall scaling success is expressed as the percentage of successful tests from the total number of scaling tests for the given scale.

A descriptive analysis of MusiQoL responses was performed and the score distributions were evaluated to identify floor and ceiling effects. Floor and ceiling effects are generally expected to appear if more than 10% of the patients responded with the lowest or highest possible score. The internal consistency of MusiQoL was evaluated using Cronbach's alpha coefficient. A Cronbach's alpha of >0.7 is considered having a high degree of internal consistency.<sup>9</sup> A too high correlation (i.e. >0.95) among the items, however, suggests a redundancy of one or more items in this scale.<sup>10</sup>

As a measure for external validity, construct validity shows that the instrument under evaluation correlates significantly with established similar measures in the expected direction and magnitude. Two aspects of construct validity of the MusiQoL were evaluated: Convergent and divergent construct validities were assessed using Spearman's rank correlation coefficients. The strength of correlation coefficients was defined according to Cohen<sup>11</sup>: >0.5 (strong); 0.3–0.5 (moderate); 0.1–0.3 (weak); <0.1 (trivial). Based on the assumption that scores from similar scales would correlate more highly than scores from dissimilar scales,

the following a 19 priori hypotheses were generated: (a) ADL scores would correlate moderately with SF-36 PF and RP and weakly with MH scales; (b) PWB would correlate moderately with the SF-36 MH and weakly with PF scales; (c) SPT would correlate moderately with SF-36 RP and VT scales; (d) RFr would correlate weakly with SF-36 PF and moderately with MH scales; (e) RFa would correlate weakly with SF-36 PF and moderately with MH scales; (f) RHCS would correlate weakly with SF-36 PF and MH scales; (g) SSL would correlate weakly with SF-36 PF and MH scales; (h) COP would correlate weakly with SF-36 PF and BP scales; (i) REJ would correlate moderately with SF-36 RP and RE scales, and (j) MusiQoL scores (with the exception of ADL) would correlate weakly with 4 clinical indices of MS (EDSS, AI, MMSE and CGI). At least 75% of the results should be in accordance with a priori hypotheses.<sup>10</sup> Divergent construct validity results if weak correlations are expected between domains measuring dissimilar constructs.

Additionally, we assessed known-groups validity by generating the following a priori hypotheses: (a) PWB, RFr and SPT scores would be lower in women than in men; (b) MusiQoL scores would be lower in non-working patients with the exception of RFr and RFa; (c) patients with mild disease would have better ADL scores than those with moderate or severe disease. We performed tests of hypotheses for between-group comparisons with the Wilcoxon rank sum test.

All statistical analyses were performed using STATA software (STATA Corp, College Station, TX).

## Results

### Patient Demographics

A total of 81 MS patients from Singapore (n = 23), Malaysia (n = 22), and India (n = 36) were included in the study. For the Malaysian sample, 14 of 22 patients were without case report form and for the Indian sample, data were missing (items 12a – 12n) from all patients for the symptoms scores.

Among those patients who answered the respective questions, the median age was 42.7 years, 78% were female, 70% were married, 31.1% were unemployed, and 47% attained a tertiary educational level. The MMSE (mean: 28.5) was within available norms.<sup>12</sup> The most common pattern was the relapsing-remitting variant (70%), which was assessed as being mild in 64.9%. No significant differences were found between countries in terms of disability. Detailed characteristics of the included patients are presented in Table 1.

### Assessment of Patient Acceptability and Content Validity

The MusiQoL was generally well accepted; none of the subjects reported that they were unclear about some

Table 1. Patient Characteristics

Parameter	N (%) unless specified
Mean age (years), n = 61	42.7
Female, n = 64	50 (78%)
Married, n = 64	45 (70%)
Years of Education, n = 66	
0 – 6 (Primary)	7 (10.6%)
7 – 10 (Secondary)	28 (42.2%)
>10 (Tertiary)	31 (47%)
Employed, n = 61	42 (68.9%)
With comorbid medical conditions, n = 63	15 (23.8%)
Mean Expanded Disability Status Scale Scores (range, 0 to 10), n = 56	3.4
Mean Ambulation Index Scores (range, 0 to 10), n = 58	2.8
Mean Mini Mental State Examination Scores (range, 0 to 30), n = 63	28.5
Poser classifications for multiple sclerosis, n = 62	
Clinically defined	58 (93.5%)
Laboratory supported	4 (6.5%)
Multiple sclerosis classifications, n = 60	
Relapsing-remitting	42 (70%)
Primary progressive	2 (3.3%)
Secondary progressive	16 (26.7%)
Clinical Global Impression, n = 37	
Mild	24 (64.9%)
Moderate	8 (21.6%)
Severe	5 (13.5%)

MusiQoL items. Seven patients highlighted some content area that they felt was important but was not included in the questions: An insufficient insurance coverage as well as no government support for MS patients in Singapore, medical expenses and strain on resources with medicine, uncertainty due to their condition, a possibly great impact of spiritual life on patient's life, and how nutrition and exercise may benefit patients.

### Psychometric Property Analysis

For the data from Singapore and Malaysia, item-internal consistency was excellent, with scaling success reaching 100% for all 9 scales (Table 2). Item-discriminant validity was also generally good, with scaling success exceeding 69% for all the scales. The item-internal consistency for the Indian data was acceptable, with scaling success reaching 100% for 5 of 9 scales (Table 2). However, 2 scales ('coping' and 'rejection') were not scored as there were more than

Table 2. Item-internal Consistency and Discriminant Validity of the MusiQoL

MusiQoL domains and items	Combined data from Singapore and Malaysia			Data from India		
	Item internal consistency	Item discriminant validity		Item internal consistency	Item discriminant validity	
	Item-scale correlation coefficients (corrected for overlaps)	% Scaling success*	% Scaling success†	Item-scale correlation coefficients (corrected for overlaps)	Scaling success†	% Scaling success†
Activities of daily living		100	77		100	89
Item 1	0.89			0.82		
Item 2	0.90			0.89		
Item 3	0.85			0.82		
Item 4	0.85			0.93		
Item 5	0.78			0.64		
Item 6	0.76			0.84		
Item 7	0.62			0.61		
Item 8	0.81			0.82		
Physical well being		100	84		100	78
Item 9	0.74			0.70		
Item 10	0.78			0.79		
Item 11	0.79			0.69		
Item 12	0.57			0.57		
Symptoms		100	91		50	94
Item 13	0.53			0.40		
Item 14	0.59			0.56		
Item 15	0.42			0.38		
Item 16	0.51			0.37		
Relationships with friends		100	79		100	92
Item 17	0.71			0.76		
Item 18	0.85			0.84		
Item 19	0.59			0.61		
Relationships with family		100	75		100	96
Item 20	0.78			0.80		
Item 21	0.86			0.95		
Item 22	0.72			0.93		
Relation with healthcare system		100	79			100
Item 23	0.80			0.76		
Item 24	0.87			0.72		
Item 25	0.76			0.79		
Sentimental and sexual life		100	69		100	88
Item 26	0.59			0.50		
Item 27	0.59			0.50		
Coping		100	100		0	88
Item 28	0.77			0.33		
Item 29	0.77			0.33		
Rejection		100	88		0	94
Item 30	0.62			0.38		
Item 31	0.62			0.38		

\* Scaling success (convergent validity) refers to the number of item-scale correlations (corrected for overlaps) exceeding 0.40, expressed as a percentage of the total number of scaling tests for a given scale.

† Scaling success (divergent validity) refers to the number of item-scale correlations (corrected for overlaps) below 0.40 for unrelated scales, expressed as a percentage of the total number of scaling tests for the given scale.

Table 3A. Distribution, Internal Consistency and Test-retest Reliability of MusiQoL scale Scores (Combined Data from Singapore and Malaysia)

Scale	Median scale scores* (interquartile range)	Floor%	Ceiling%	Missing data%	Internal consistency†
Activities of daily living	56.1 (51.6, 71.9)	4	2	0	0.94
Psychological well being	57.2 (43.8, 78.1)	0	9	0	0.86
Symptoms	68.8 (56.3, 87.5)	0	13	0	0.71
Relation with friends	72.3 (54.2, 91.7)	0	16	0	0.80
Relation with family	80.0 (58.3, 100)	2	31	0	0.91
Relation with health care system	73.9 (54.2, 95.8)	0	24	0	0.89
Sentimental and sexual life	74.1 (50.0, 75.0)	0	11	0	0.72
Coping	56.9 (50.0, 87.5)	11	13	0	0.87
Rejection	75.0 (67.1, 100)	4	40	0	0.79
Global MusiQoL score	67.7 (59.1, 78.4)	0	0	0	-

\* Scale scores ranged from 0 to 100, with higher scores indicating better health-related quality of life.

† Internal consistency assessed using Cronbach's alpha (alpha coefficient of at least 0.7 expected for each scale).

Table 3B. Distribution, Internal Consistency and Test-retest Reliability of MusiQoL Scale Scores (Data from India)

Scale	Median scale scores* (interquartile range)	Floor%	Ceiling%	Missing data%	Internal consistency†
Activities of daily living	56.1 (49.2, 58.6)	3	3	0	0.92
Psychological well being	56.3 (31.3, 68.8)	8	6	0	0.87
Symptoms	68.6 (51.3, 81.3)	3	11	0	0.69
Relation with friends	79.2 (66.7, 100)	0	31	0	0.85
Relation with family	100 (75.0, 100)	0	56	0	0.91
Relation with health care system	75.0 (66.7, 100)	0	33	0	0.86
Sentimental and sexual life	75.0 (74.1, 100)	3	36	0	0.75
Coping	50.0 (37.5, 75.0)	6	8	0	0.49
Rejection	71.7 (50.0, 87.5)	6	22	0	0.60
Global MusiQoL score	69.3 (58.0, 76.6)	0	0	0	-

\* Scale scores ranged from 0 to 100, with higher scores indicating better health-related quality of life.

† Internal consistency assessed using Cronbach's alpha (alpha coefficient of at least 0.7 expected for each scale).

50% of the items missing. Item-discriminant validity for the Indian data was generally good, with scaling success exceeding 78% for all scales.

The distribution of the data scores from Singapore and Malaysia is presented in Table 3A. Floor effect exceeded 10% in 1 of 9 scales, while ceiling effect exceeded 10% in 7 of 9 scales. The ceiling effect was particularly high (40%) for 'rejection'. All scales exhibited good internal consistency (Cronbach's alpha >0.70). The distribution of the data scores from India is presented in Table 3B. None of the scales exceeded 10% in the floor effect, while ceiling effect exceeded 10% in 6 of 9 scales. The ceiling effect was particularly high (56%) for the item 'relation with family'. Three scales ('symptoms', 'coping' and 'rejection') did not reach internal consistency (Cronbach's alpha <0.70).

However, these measures gave us information about vitality (fatigue), emotional status and mental health which had not been picked up by the EDSS.

Tests of construct validity were carried out for data from Singapore and India. Table 4 presents Spearman's rank correlation coefficients among MusiQoL and selected SF-36 scales. For the combined data from Singapore and India, of 19 a priori hypotheses, 16 (84.2%) were met, thus strengthening the convergent and divergent validity of the Asian adaptation of the MusiQoL. Spearman's rank correlation coefficients between MusiQoL scales and other clinical indices of MS are also shown in Table 4. As hypothesised, MusiQoL scale scores correlated weakly with all 4 clinical indices of MS, providing further support for the convergent and divergent validity of the Asian



Table 4. Tests of Construct Validity: Spearman's Rank Correlation Coefficients (Data from Singapore and India)

	MusiQoL								
	ADL	PWB	SPT	RFr	RFa	RHCS	SSL	COP	REJ
<b>SF36<sup>§</sup></b>									
Physical functioning	<b><u>0.56</u></b> <sup>‡</sup>	0.32*	0.27	<b><u>0.22</u></b>	<b><u>0.15</u></b>	<b><u>-0.14</u></b>	<b><u>-0.01</u></b>	<b><u>0.26</u></b>	0.20
Role-physical	<b><u>0.46</u></b> <sup>‡</sup>	0.45 <sup>‡</sup>	<b><u>0.37</u></b> <sup>‡</sup>	0.32	0.29*	0.03	-0.03	0.50 <sup>‡</sup>	<b><u>0.43</u></b> <sup>‡</sup>
Bodily pain	0.03	0.07	0.29*	-0.13	-0.11	0.03	0.06	<b><u>-0.05</u></b>	0.10
Vitality	0.45 <sup>‡</sup>	0.52 <sup>‡</sup>	<b><u>0.49</u></b> <sup>‡</sup>	0.16	0.42 <sup>‡</sup>	0.17	0.14	0.58 <sup>‡</sup>	0.30*
Role-emotional	0.34 <sup>‡</sup>	0.49 <sup>‡</sup>	0.31*	0.26	0.37 <sup>‡</sup>	0.04	0.16	0.62 <sup>‡</sup>	<b><u>0.37</u></b> <sup>‡</sup>
Mental health	0.42 <sup>‡</sup>	<b><u>0.61</u></b> <sup>‡</sup>	0.40 <sup>‡</sup>	<b>0.15</b>	<b><u>0.38</u></b> <sup>‡</sup>	<b><u>0.16</u></b>	<b><u>0.18</u></b>	0.65 <sup>‡</sup>	0.29*
<b>Clinical indices of multiple sclerosis</b>									
Expanded Disability Status Scale	-0.41 <sup>‡</sup>	-0.13	-0.02	-0.41 <sup>‡</sup>	-0.21	-0.26	-0.15	-0.16	-0.17
Ambulation Index	-0.25	-0.06	-0.16	-0.25	-0.23	-0.16	-0.02	-0.08	-0.21
Mini Mental State Examination	0.04	-0.07	-0.08	-0.08	-0.02	-0.27	0.09	0.12	0.003
Clinical Global Impression	-0.54 <sup>‡</sup>	-0.10	-0.24	-0.19	0.05	-0.31	-0.32	0.01	-0.17

\* $P < 0.05$ ; <sup>‡</sup> $P < 0.01$ ; <sup>‡‡</sup> $P < 0.001$ 

§ Figures in bold correspond to tests of convergent construct validity, while figures in bold italics correspond to tests of divergent construct validity, with supported hypotheses being underlined.

Note: Spearman's rank correlation coefficients are not shown for scales without a priori hypothesis.

ADL: activity of daily living; PWB: psychological well being; SPT: symptoms; RFr: relationships with friends; RFa: relationships with family; RHCS: relationships with health care system; SSL: sentimental and sexual life; COP: coping; REJ: rejection

Table 5. Known-groups Construct Validity of MusiQoL (Singapore and India)

Subgroups	Median MusiQoL scale scores (Interquartile range)								
	ADL	PWB	SPT	RFr	RFa	RHCS	SSL	COP	REJ
<b>Gender</b>									
Female (n = 13)	56.1 (51.5, 63.3)	<b><u>56.3</u></b> ( <b><u>39.1, 68.8</u></b> )	<b><u>68.6</u></b> ( <b><u>56.3, 81.3</u></b> )	<b><u>72.3</u></b> ( <b><u>50.0, 91.7</u></b> )	81.77 (60.4, 100)	74.5 (58.3, 100)	74.1 (74.1, 100)	50.0 (40.6, 75.0)	75.0 (53.1, 87.5)
Male (n = 44)	56.1 (40.6, 75.0)	<b><u>62.5</u></b> ( <b><u>37.5, 68.8</u></b> )	<b><u>75.0</u></b> ( <b><u>53.1, 100</u></b> )	<b><u>75.0</u></b> ( <b><u>69.5, 87.5</u></b> )	91.7 (66.7, 100)	73.9 (45.8, 79.2)	74.1 (50.0, 100)	62.5 (43.8, 81.3)	87.5 (71.7, 100)
<b>Employment status</b>									
Yes (n = 24)	<b><u>57.8</u></b> ( <b><u>53.9, 80.5</u></b> ) <sup>‡</sup>	<b><u>71.9</u></b> ( <b><u>45.3, 87.5</u></b> ) <sup>*</sup>	<b><u>71.9</u></b> ( <b><u>57.8, 98.4</u></b> )	<b><u>73.7</u></b> ( <b><u>60.4, 91.7</u></b> )	<b><u>85.8</u></b> ( <b><u>68.7, 100</u></b> )	<b><u>73.9</u></b> ( <b><u>60.4, 81.3</u></b> )	<b><u>74.1</u></b> ( <b><u>65.4, 100</u></b> )	<b><u>62.5</u></b> ( <b><u>50.0, 96.9</u></b> ) <sup>‡</sup>	<b><u>87.5</u></b> ( <b><u>71.7, 100</u></b> ) <sup>‡</sup>
No (n = 30)	<b><u>56.1</u></b> ( <b><u>35.9, 56.1</u></b> )	<b><u>53.1</u></b> ( <b><u>29.7, 62.5</u></b> )	<b><u>68.6</u></b> ( <b><u>54.7, 76.6</u></b> )	<b><u>66.7</u></b> ( <b><u>47.9, 85.4</u></b> )	<b><u>81.7</u></b> ( <b><u>56.2, 100</u></b> )	<b><u>73.9</u></b> ( <b><u>50.0, 100</u></b> )	<b><u>74.1</u></b> ( <b><u>68.0, 90.6</u></b> )	<b><u>50.0</u></b> ( <b><u>25.0, 56.9</u></b> )	<b><u>71.7</u></b> ( <b><u>37.5, 78.1</u></b> )
<b>Clinical Global Impression</b>									
Mild (n = 21)	<b><u>56.1</u></b> ( <b><u>56.1, 68.8</u></b> ) <sup>‡</sup>	56.3 (28.1, 68.8)	68.6 (62.5, 81.3)	72.3 (62.5, 79.2)	75.0 (58.3, 95.8)	75.0 (58.3, 100)	74.1 (74.1, 81.3)	50.0 (25.0, 56.9)	71.7 (67.1, 100)
Moderate/ Severe (n = 9)	<b><u>12.5</u></b> ( <b><u>3.1, 56.1</u></b> )	43.8 (12.5, 72.3)	62.5 (40.6, 75.0)	58.3 (50.0, 95.8)	80.0 (54.2, 100)	58.3 (37.5, 74.5)	74.1 (43.8, 74.5)	50.0 (25.0, 81.3)	75.0 (31.3, 75.0)

\* $P < 0.05$ ; <sup>‡</sup> $P < 0.01$ ; <sup>‡‡</sup> $P < 0.001$ 

Figures in bold correspond to hypothesised relationships, with supported hypotheses being underlined.

ADL: activity of daily living; PWB: psychological well being; SPT: symptoms; RFr: relationships with friends; RFa: relationships with family; RHCS: relationships with health care system; SSL: sentimental and sexual life; COP: coping; REJ: rejection

adaptation of MusiQoL. Weak correlations were observed with 'relationship to friends' and 'relationship to health-care system', as well as 'sentimental & sexual life' and 'bodily pain' of the SF-36 questionnaire.

Additional subgroup analyses of MusiQoL scores by gender, employment status and clinical global impression are shown in Table 5. For the combined data from Singapore and India, 10 (76.9%) of 13 hypotheses were in the hypothesised direction, with 2 reaching statistical significance, demonstrating support for the known-groups construct validity of the Asian adaptation of MusiQoL.

## Discussion

This study shows that the Asian adaptation of the English version of the MusiQoL is well accepted by patients. Areas of importance to MS patients showed relevant and generally comprehensive coverage, as demonstrated by the high construct validity. The MusiQoL exhibited good psychometric properties. However, several aspects of the results deserve comment.

Firstly, at the scale level, ceiling effects were above 10% in 7 of 9 (Singapore and Malaysia) and 6 of 9 (Indian data) MusiQoL scales. Small or moderate floor and ceiling effects demonstrate the ability of the questionnaire to differentiate between the various levels of a particular HRQoL status under question. For the Singapore and Malaysia sample, the ceiling effect was particularly high for the 'rejection' scale. The high ceiling effect in this scale could also have contributed to the high internal consistency observed. The ceiling effects were also high for the scales 'relation with friends', 'relation with family', and 'relation with health-care system'. This may reveal a different attitude of the patients with other cultural background towards questions of a potentially sensitive nature. In the data from India, the ceiling effect was highest for 'relation with family' and 'sentimental and sexual life'. In order to address the issue of floor and ceiling effects, item modification or addition may be considered.

For the Indian data, 3 scales ('symptoms', 'coping' and 'rejection') did not reach internal consistency (Cronbach's  $\alpha < 0.70$ ). This may be partly due to the small size (only 2 items) of some of these scales, as Cronbach's  $\alpha$  is dependent upon the number of items in a scale,<sup>10</sup> or it may be influenced by social issues of the patients.

Additionally, the missing data rate was particularly high as it was an observational study. The low rate of available re-tests may originate from the necessity of patients from the participating countries to self-fund their medical treatment; they may therefore not return for follow-up visits.

Spearman's correlations between MusiQoL and SF-36 scores and comparison of MusiQoL scores with Clinician's

Global Impression (CGI) for all studies were generally in the same direction. However, the strength of association differed for some comparisons. A reason for this could be the smaller sample size in this study. The significant differences between gender in the dimensions PWB, SPT, and RFr were also observed in the original validation study for the MusiQoL.<sup>2</sup> The results of this study are largely consistent with the international validation study of the MusiQoL,<sup>2</sup> which lends further support to the validity of the Asian adaptation of this questionnaire.

We are aware that the statistical power of our study was limited due to the small sample size. This is related to the low prevalence of MS in this population. In summary, this study supports the patient acceptability, internal consistency, reliability, and validity of the Asian adaptation of the English version of the MusiQoL in evaluating HRQoL in MS patients in Southeast Asia as well as in India. It is a suitable tool for the evaluation of patients' health status aspects not analysable by clinical assessment.

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