CHAPTER IV

Developing and Testing Results

Item generation

After an extensive review of the existing childhood SLE and HRQOL literature and HRQOL measures, 65 items were derived. (Table 1)

Table 1 Derived items and the original instruments

	Original Instruments (sentences)
Physical Health Domain	
1. ฉันเจ็บ หรือ คัน หรือ แสบที่บริเวณผิวหนัง	*
2. ฉันเบื่ออาหาร	*
3. ฉันปวดท้องมากจนไม่อยากขยับตัว	*
4. ฉันปวดตามข้อหรือตามกล้ามเนื้อมากจนไม่อยากขยับตัว	LupusQoL (The pain due to my Lupus is so severe that it limits my mobility.)
5. ฉันปวดหัว หรือ เวียนหัวจนต้องกินยาหรือพักผ่อน	*
6. ฉันนอนไม่ค่อยหลับเพราะอาการปวดต่างๆ ของฉัน	PedsQL™ Rheumatology module (I have trouble sleeping because of pain or aching in my joints and/or muscles.)
7. ฉันรู้สึกทรมานเพราะอาการปวดต่างๆ ของฉัน	PedsQL™ Rheumatology module (I hurt a lot.)
8. ฉันอ่อนเพลีย ไม่ค่อยมีเรี่ยวแรง	PedsQL™ (I have low energy.)
9. ฉันไม่สบายบ่อยจนไม่ได้ทำสิ่งที่ฉันต้องการ	PSDQ (I am sick so often that I cannot do all the things I want to do.)
10. ฉันป่วยหนักจนไม่สามารถลุกจากเตียงนอนเองได้	PSDQ (I am sick so often that I cannot do all the things I want to do.)

*Items developed by the investigator; PedsQL™, the Pediatric Quality of Life Inventory™; PSDQ, Physical Self-Description Questionnaire; PODCI/POSNA, Pediatric Outcomes Data Collection Instruments.

Table 1 Derived items and the original instruments (cont.)

	Original Instruments (sentences)
Daily Activity Domain	
1. การเดินบนพื้นราบภายในบ้านเป็นเรื่องยากลำบากสำหรับฉัน	*
2. การเดินขึ้นบันไดเป็นเรื่องยากลำบากสำหรับฉัน	*
3. การวิ่งเป็นเรื่องยากลำบากสำหรับฉัน	PedsQL™ (It is hard for me to run.)
4. การติดกระดุมเสื้อด้วยตนเองเป็นเรื่องยากลำบากสำหรับฉัน	PODCI/POSNA
5. การหยิบจับช้อน-ซ้อมเป็นเรื่องยากลำบากสำหรับฉัน	PedsQL™ Rheumatology module (I have trouble eating with a fork and knife)
6. การหวีผมด้วยตนเองเป็นเรื่องยากลำบากสำหรับฉัน	PODCI/POSNA (It is hard for you to comb your hair.)
7. การก้มหยิบของจากพื้นเป็นเรื่องยากลำบากสำหรับฉัน	PODCI/POSNA (It is hard for you to bend over from a standing position and pick up something off the floor.)
8. การอาบน้ำด้วยตนเองเป็นเรื่องยากลำบากสำหรับฉัน	PedsQL™ (It is hard for me to take a bath or shower by myself.)
9. เป็นเรื่องยากลำบากสำหรับฉันที่จะยกของหนัก	PedsQL™ (It is hard for me to lift something heavy.)
10. มือของฉันมีปัญหาจนลำบากในการเขียนหนังสือ	PODCI/POSNA (It is hard for you to write with a pencil.)
Family Domain	
1. พ่อ แม่ หรือผู้เลี้ยงดูฉันมีภาระที่เพิ่มขึ้น	LupusQoL (I am a burden to my friends and/or family.)
2. พ่อ แม่ หรือผู้เลี้ยงดูฉันไม่สบายใจ	LupusQoL (I cause worry to those who are close to me.)
3. พ่อ แม่ หรือผู้เลี้ยงดูไม่เข้าใจฉัน	KIDSCREEN-52 (Have your parent(s) understood you?)
4. เป็นเรื่องยากสำหรับฉันที่จะคุยกับพ่อ แม่ หรือผู้เลี้ยงดูเมื่อฉันมีปัญหา	KIDSCREEN-52 (Have you been able to talk to yous parent(s) when you wanted to?)
Treatment Domain	
1. การรักษาหรือยาที่ฉันได้รับไม่ได้ช่วยรักษาโรคของฉัน	PedsQL™ Rheumatology module (I worry about whether or not my medicines are working.)
2. การรักษาหรือยาที่ฉันได้รับทำให้ฉันรู้สึกไม่สบาย	PedsQL™ Rheumatology module (My medicines make me feel sick.)

Table 1 Derived items and the original instruments (cont.)

	Original Instruments (sentences)
Treatment Domain (cont.)	
3. โรคลูปัสของฉันยากที่จะรักษา	PedsQL™ Rheumatology module (It is hard to manage my illness.)
4. ฉันกลัวที่จะถูกเจาะเลือดหรือถูกฉีดยา	PedsQL™ Rheumatology module (I get scared when I have to have blood tests; I get scared about having needle sticks/shots.)
5. ฉันกลัวที่จะต้องไปหาหมอ	PedsQL™ Rheumatology module (I get scared when I have to go the doctor.)
6. ฉันกังวลในเรื่องผลข้างเคียงของยาหรืออาการแพ้ยา	PedsQL™ Rheumatology module (I worry about the side effects from medicines.)
7. เป็นเรื่องยากสำหรับฉันที่จะบอกหมอหรือพยาบาลเกี่ยวกับปัญหาที่ฉันมี	PedsQL™ Rheumatology module (It is hard for me to tell the doctors and nurses how I feel.)
8. เป็นเรื่องยากสำหรับฉันที่จะบอกคนอื่นๆให้รู้เกี่ยวกับโรคของฉัน	PedsQL™ Rheumatology module (It is hard for me to explain my illness to other people.)
9. เป็นเรื่องยากสำหรับฉันที่จะใช้ยาตามที่หมอสั่ง	*
10. เป็นเรื่องยากสำหรับฉันที่จะปฏิบัติตัวตามที่หมอแนะนำ	*
11. ฉันเบื่อหน่ายกับการใช้ยาหรือการปฏิบัติตัวตามที่หมอแนะนำ	*
12. ฉันเบื่อหน่ายกับการที่ต้องมาหาหมอเป็นประจำ	*
Emotional Health Domain	
1. ฉันรู้สึกเศร้า	PedsQL™ (I feel sad or blue.)
2. ฉันรู้สึกโกรธ	PedsQL™ (I feel angry.)
3. ฉันรู้สึกโดดเดี่ยว	KIDSCREEN-52 (Have you felt lonely?)
4. ฉันรู้สึกว่าฉันเป็นคนที่โชคร้าย	*
5. ฉันนอนไม่ค่อยหลับเพราะไม่สบายใจเกี่ยวกับโรคของฉัน	*
6. ฉันรู้สึกไม่พอใจกับหน้าตาหรือรูปร่างของตัวเอง	PSDQ (Physically I feel good about myself.)

Table 1 Derived items and the original instruments (cont.)

	Original Instruments (sentences)
Emotional Health Domain (cont.)	
7. ฉันอิจฉาในหน้าตาหรือรูปร่างของคนอื่น	KIDSCREEN-52 (Have you felt jealous of the way other girls and boys look?)
8. ฉันขาดความเชื่อมั่นในตนเอง ไม่กล้าพูดหรือแสดงความคิดเห็นต่อหน้าผู้อื่น	*
9. ฉันกังวลว่าจะเกิดอะไรขึ้นกับฉันถ้ามีโรคกำเริบ	PedsQL™ (I worry about what will happen to me.)
Social Domain	
1. เป็นเรื่องยากสำหรับฉันที่จะเข้ากับกลุ่มเพื่อนวัยเดียวกัน	PODCI/POSNA (It is hard for you to make friends with kids your own age.)
2. ฉันอายจนไม่อยากจะเข้ากับกลุ่มเพื่อน	*
3. ฉันไม่รู้สึกสนุกเมื่ออยู่ในกลุ่มเพื่อน	KIDSCREEN-52 (Have you had fun with your friends?)
4. ฉันอายจนไม่อยากจะออกไปเจอคนอื่นๆ นอกบ้าน	LupusQoL (my appearance, e.g. rash, weight gain/loss, makes me avoid social situations.)
5. เด็กคนอื่นไม่อยากเป็นเพื่อนกับฉัน	PedsQL™ (Other teens do not want to be my friend.)
6. ฉันถูกเพื่อนหรือเด็กอื่นๆ ล้อเลียน หรือกลั่นแกล้ง	PedsQL™ (Other teens tease me.) KIDSCREEN-52 (Have other girls and boys bullied you?)
7. ฉันไม่สามารถทำในสิ่งที่เด็กวัยเดียวกันทำได้	PedsQL™ (I cannot do things that other teens my age can do.)
8. เป็นเรื่องยากที่ฉันจะเรียนรู้และตามทันเด็กในวัยเดียวกัน	PedsQL™ (It is hard to keep up with my peers.)
9. ฉันไม่สามารถเข้าร่วมกิจกรรมกับเพื่อนๆ เช่นไปเที่ยว เข้าค่าย ไปทัศนศึกษา	KIDSCREEN-52 (Have you done things with other girls and boys?)
10. เป็นเรื่องยากที่ฉันจะช่วยเหลืองานของพ่อ แม่หรือผู้เลี้ยงดู	*
Schooling Domain	
1. เป็นเรื่องยากที่ฉันจะจดจ่อตั้งใจฟังสิ่งที่ครูสอน	KIDSCREEN-52 (Have you been able to pay attention?)
2. เป็นการยากที่ฉันจะเข้าใจสิ่งที่ฉันเรียนหรือที่อ่าน	*
3. ฉันหลงลืมสิ่งต่างๆ ที่ฉันเรียนหรือที่อ่าน	*
4. ฉันไม่อยากไปโรงเรียน	KIDSCREEN-52 (Have you enjoyed going to school?)

Table 1 Derived items and the original instruments (cont.)

	Original Instruments (sentences)
Schooling Domain (cont.)	
5. ฉันต้องขาดเรียนเพราะไม่สบาย	PedsQL™ (I miss school because of not feeling well.)
6. ฉันขาดเรียนเพราะต้องไปหาหมอหรือไปโรงพยาบาล	PedsQL™ (I miss school to go to the doctor or hospital.)
7. ฉันสิ้นหวังในอนาคตทางการเรียนของฉัน	*
Finance Domain	
1. พ่อ แม่ หรือผู้เลี้ยงดูฉันไม่มีเงินพอส่งให้ฉันเรียนหนังสือ	*
2. พ่อ แม่ หรือผู้เลี้ยงดูฉันไม่มีเงินเก็บพอให้ฉันไปเที่ยวหรือทำกิจกรรมกับเพื่อน	KIDSCREEN-52 (Do you have enough money to do things with your friends?)
3. พ่อ แม่ หรือผู้เลี้ยงดูฉันไม่มีเงินเก็บพอให้ฉันซื้อของที่อยากได้	KIDSCREEN-52 (Have you had enough money for your expenses?)

*An item developed by the investigator; PedsQL™, the Pediatric Quality of Life Inventory™; PSDQ, Physical Self-Description Questionnaire; PODCI/POSNA, Pediatric Outcomes Data Collection Instruments.

By January-February 2008, we discuss a group of 7 pediatric nephrologists, 3 pediatricians and 2 nurses who are cognizant of the QOL issues and experience in managing SLE adolescents, and a pediatric psychiatrist to consider these items of which each was carefully worded to ensure that it relates specifically to SLE, and where possible the patients' terminology is used. One new item was added. The content validity index (CVI) of each item was calculated according to the scoring ranged -1.0 to 1.0 by our seven pediatric nephrologists. The average of CVI was 0.81 with a standard deviation of 0.14.

Pre-testing the questionnaire

In April-May 2008, 30 eligible patients and their parents were asked to criticize/make comments about the design, content, structure, and response scale of the questionnaire and to suggest activities in their lives that had been affected by their

illness that had been omitted in the questionnaire. Written comments were received from 13.3% of patients and were carefully studied. Amendment was made: 3 questions were rephrased because they were irrelevant for the patients. No new items were suggested. The questionnaire had 8 hypothesized domains comprising physical health (10 items), dairy activity (10 items), family (4 items), treatment (13 items), emotional health (9 items), social (10 items), schooling (7 items), and finance (3 items).

Field-testing the revised questionnaire (QoLMEAL)

During June-December 2008, QoLMEAL consisting of these 66 self-administered questions were completed by 123 parents and 128 patients at one of four medical school hospitals in Bangkok. The patients were 98 girls and 30 boys with a mean age of 14.5 years (range 10.0-18.6 years). Table 2 shows the patients' demographic characteristics. The mean age at diagnosis was 10.9 years (range 4.4-14.7 years) and mean duration of the disease was 3.5 years (range 0.3-11.4 years). Most patients (94.4%) remained to continue their studies in the school. With respect to educational level, 2.4%, 20%, 75.2% and 2.4% had primary, middle, high school and undergraduate education, respectively. 13% of the patients' families were in debt even though almost 80% had enough money to expense.

Table 3 shows the patients' clinical characteristics and their treatments. Based on ECLAM and SDI scores, 48.5% of patients had no current disease activity and 59.8% had no damage, respectively. The mean ECLAM score was 1.1 (range 0–7, n=101), and mean SDI score was 0.4 (range 0–2, n=122). Because 6 of 128 patients had SLE duration of less than 6 months at the time of enrollment, we did not report their SDI scores. ECLAM scores of 27 patients were not analyzed because of an incomplete assessment, mostly in the items of serology. Mean body mass index of all patients was 22.5 kg/m^2 with a standard deviation of 5.5 kg/m^2. Of 128 patients with mean disease duration of 3.5 years, 91.4% had been diagnosed with SLE for more than 1 year. 18 patients (14.2%) had a history of hospitalization within the past one month prior to the entry of study. 11 of 18 patients were admitted due to intravenous cyclophosphamide.

Table 2 Demographic Characteristics of 128 patients

Characteristic	N	Mean (SD) or Number (%)
Mean Age (years)	128	14.5 (1.9)
Mean Age of diagnosis (years)	128	10.9 (2.4)
Mean duration of SLE (years)	128	3.5 (2.3)
Gender	128	
Female		98 (76.6%)
Male		30 (23.4%)
Educational status	125	
Being in school		118 (94.4%)
School absence < 1 year		2 (1.6%)
School absence ≥ 1 year		5 (4.0%)
Educational level	125	
Primary school		3 (2.4%)
Middle school		25 (20%)
High school (the first 3 years)		70 (56%)
High school (the last 3 years)		24 (19.2%)
Undergraduate		3 (2.4%)
Medical Insurance	127	
No insurance		9 (7.1%)
Government welfare		24 (18.9%)
Social security		3 (2.4%)
Nation health security		89 (70.1%)
Private insurance		2 (1.6%)
Family financial status	123	
Enough money for savings		46 (37.4%)
Enough money but no savings		51 (41.5%)
No enough money but without debts		10 (8.1%)
No enough money and with debts		16 (13.0%)

63 patients (49.2%) received only steroid and 63 patients (49.2%) received steroid plus another immunosuppressant such as cyclophosphamide, azathioprine, or mycophenolate. One had no immunosuppressant and the other received three drugs.

Table 3 Clinical characteristics and the treatments of 128 patients

Characteristic	N	Mean (SD) or Number (%)
Body mass index (kg/m^2) (SD)	128	22.5 (5.5)
ECLAM score (SD)	101	1.1 (1.6)
SDI score (SD)	122	0.4 (0.6)
Hospitalization within the past month	127	18 (14.2%)
ICU admission within the past month	127	1 (0.8%)
Immunosuppressants within the past month		
Steroids	128	127 (99.2%)
Cyclophosphamide	127	29 (22.8%)
Azathioprine	128	21 (16.4%)
Mycophenolate	128	16 (12.5%)
Cyclosporine	128	-

Item-level analysis

Table 4 shows the proportion of patients whose responses reached the maximum and minimum scores in each domain of the QoLMEAL. The ceiling or floor effect possibly occurs when patients perceive that their condition has improved or deteriorated, respectively, beyond what a QOL questionnaire can measure. In this case, the floor values consistently represent well perceived QOL and ceiling values poor QOL. There were no ceiling effects for our patients but floor effects existed in some cases. These effects were minimal in the self- and proxy-report total scale score (0.9 and 3.6, respectively) and maximal in the self-report finance and proxy-report daily activity domain score (49.2 and 46.7, respectively).

Table 4 The QoLMEAL summary data, floor and ceiling effects, and missing responses: *128 adolescent report and 123 parent report.*

Domains (no. of items in domain)	Total scores, mean (SD, range)	Floor effects (% minimum score of 0)	Ceiling effects (% maximum score of 100)	Missing responses
Self-report				
- All domains (66)	15.3 (10.2, 0-56.8)	0.9	0	21
- Physical health (10)	15.5 (13.6, 0-65)	11.8	0	1
- Daily activity (10)	7.5 (8.8, 0-47.5)	24.0	0	3
- Family (4)	20.9 (19.2, 0-75)	24.4	0	1
- Treatment (13)	15.9 (15.4, 0-84.6)	12.2	0	5
- Emotional health (9)	21.5 (18.3, 0-83.3)	7.8	0	0
- Social (10)	12.4 (13.8, 0-82.5)	22.9	0	10
- Schooling (7)	21.8 (14.9, 0-89.3)	3.2	0	2
- Finances (3)	14.9 (18.9, 0-75)	49.2	0	0
Proxy-report				
- All domains (66)	15.1 (11.2, 0-64.8)	3.2	0	29
- Physical health (10)	15.4 (15.3, 0-72.5)	17.8	0	5
- Daily activity (10)	7.2 (11.8, 0-62.5)	46.7	0	1
- Family (4)	19.6 (19.3, 0-93.8)	31.1	0	1
- Treatment (13)	16.9 (13.8, 0-57.7)	9.0	0	12
- Emotional health (9)	20.6 (17.1, 0-69.4)	11.6	0	2
- Social (10)	13.0 (14.3, 0-67.5)	27.6	0	7
- Schooling (7)	19.1 (16.5, 0-96.4)	8.5	0	5
- Finances (3)	16.3 (19.1, 0-83.3)	44.3	0	1

Floor / ceiling effects, the percentage scores at the extremes of the scaling range; missing responses, the percentage unable to score domain.

For the self-report, 25 items were omitted out of a total of 8,448 items (66 items×128 children), with a mean (SD) number of items omitted of 0.2 (0.5). The

maximum number omitted was 3 items by one child. The most often omitted item [S10] was in the social domain. For the parent-report, 50 items were omitted out of a total of 8,118 items (66 items×123 parents). The mean (SD) number of items omitted was 0.4 (1.4). The maximum number omitted was 14 items by one parent. Two most often omitted items [T3, S10] were in the treatment and social domain.

Table 5 and 6 show the correlations between individual items and the hypothesized domains in adolescent self-report and parent proxy-report. Of adolescent self-report, the ten items comprising physical health domain (PH1-PH10) had correlations with their own domain of between 0.39 (PH10) and 0.74 (PH8), and the 70 correlations with other domains ranged from 0.10 (PH3 with S) to 0.51 (PH4 with EH). The ten daily activity items (DA1-DA10) had correlations between 0.15 (DA5 and DA6) and 0.80 (DA3) with their own domain, and the 70 correlations with other domains ranged from -0.02 (DA6 with FI) to 0.51 (DA9 with T). The four family items (F1-F4) had correlations between 0.56 (F4) and 0.85 (F2) with their own domain, and the 28 correlations with other domains ranged from 0.09 (F4 with DA) to 0.58 (F2 with EH). The thirteen treatment items (T1-T13) had correlations between 0.39 (T4 and T5) and 0.65 (T3 and T11) with their own domain, and the 91 correlations with other domains ranged from 0.03 (T4 with FI) to 0.56 (T6 with EH). The nine emotional health items (EH1-EH9) had correlations between 0.50 (EH5) and 0.74 (EH9) with their own domain, and the 63 correlations with other domains ranged from 0.14 (EH7 with FI) to 0.55 (EH9 with T). The ten social items (S1-S10) had correlations between 0.41 (S4) and 0.74 (S9) with their own domain, and the 70 correlations with other domains ranged from 0.11 (S3 with PH) to 0.49 (S9 with SC). The seven schooling items (SC1-SC7) had correlations between 0.50 (SC1) and 0.65 (SC3) with their own domain, and the 49 correlations with other domains ranged from 0.15 (SC5 with FI) to 0.55 (SC3 with T and SC7 with S). The three finance items (FI1-FI3) had correlations between 0.71 (F1) and 0.91 (F3) with their own domain, and the 21 correlations with other domains ranged from 0.10 (FI1 with S) to 0.43 (F3 with DA).

Of parent proxy-report, the ten items comprising PH domain had correlations with their own domain of between 0.46 (PH10) and 0.75 (PH4), and the 70 correlations

with other domains ranged from 0.04 (PH9 with FI) to 0.45 (PH9 with S). The ten DA items had correlations between 0.21 (DA5) and 0.84 (DA3) with their own domain, and the 70 correlations with other domains ranged from -0.02 (DA5 with FI) to 0.48 (DA9 with S). The four F items had correlations between 0.56 (F4) and 0.85 (F2) with their own domain, and the 28 correlations with other domains ranged from 0.01 (F3 with FI) to 0.58 (F2 with T). The thirteen T items had correlations between 0.44 (T4 and T9) and 0.69 (T12) with their own domain, and the 91 correlations with other domains ranged from -0.04 (T4 with FI) to 0.54 (T13 with EH). The nine EH items had correlations between 0.54 (EH7) and 0.78 (EH1) with their own domain, and the 63 correlations with other domains ranged from 0.05 (EH8 with FI) to 0.58 (EH1 with S). The ten S items had correlations between 0.37 (S4) and 0.79 (S9) with their own domain, and the 70 correlations with other domains ranged from 0.09 (S9 with FI) to 0.49 (S2 with EH and S8 with SC). The seven SC items had correlations between 0.39 (SC4) and 0.73 (SC3 and SC5) with their own domain, and the 49 correlations with other domains ranged from 0.13 (SC5 with FI) to 0.61 (SC3 with EH). The three FI items had correlations between 0.81 (F1) and 0.88 (F3) with their own domain, and the 21 correlations with other domains ranged from 0.09 (FI1 with PH) to 0.38 (F2 with SC).

Table 7 summarized the convergent and discriminant validity, scaling success, and the domain homogeneity. The convergent validity is the degree to which an item moderately to strongly correlates with (converges on) its hypothesized domain. The discriminant validity is supported if an item has a significantly higher correlation with their own domain than with other domains.

Table 5 Item-scale correlations for multitrait-scaling analysis of the QoLMEAL:

128 adolescent report

	Hypothesized domains							
	PH	DA	F	T	EH	S	SC	FI
PH1	**.617**	.231	.375	.296	.370	.139	.145	.240
PH2	**.542**	.251	.283	.337	.386	.203	.355	.193
PH3	**.568**	.263	.214	.182	.229	.101	.162	.176
PH4	**.692**	.444	.389	.484	.508	.449	.479	.177
PH5	**.633**	.253	.252	.276	.237	.222	.307	.199
PH6	**.604**	.370	.324	.372	.323	.236	.360	.120
PH7	**.704**	.331	.480	.488	.407	.389	.380	.272
PH8	**.743**	.398	.431	.469	.493	.413	.432	.248
PH9	**.577**	.444	.249	.401	.330	.369	.362	.220
PH10	**.398**	.172	.232	.222	.127	.196	.179	.126
DA1	.128	**.268**	.168	.211	.209	.251	.233	.224
DA2	.421	**.674**	.314	.417	.259	.413	.377	.212
DA3	.313	**.800**	.257	.332	.187	.301	.274	.297
DA4	.143	**.290**	.055	.064	.104	.241	.209	.025
DA5	.084	**.146**	.029	.048	.118	.060	.121	.081
DA6	.030	**.147**	.039	.126	.004	***.164***	.106	-.022
DA7	.282	**.531**	.140	.278	.097	.403	.268	.236
DA8	.114	**.209**	.083	.083	.046	.143	.127	.094
DA9	.462	**.746**	.369	.506	.364	.444	.411	.293
DA10	.428	**.490**	.335	.353	.298	.368	.294	.286
F1	.336	.301	**.796**	.471	.419	.410	.367	.382
F2	.419	.407	**.852**	.452	.578	.415	.358	.371
F3	.357	.187	**.584**	.318	.351	.234	.192	.179
F4	.352	.098	**.559**	.304	.417	.230	.187	.181
T1	.318	.135	.357	**.493**	.415	.376	.349	.190
T2	.399	.315	.421	**.586**	.387	.405	.355	.278
T3	.406	.329	.392	**.648**	.413	.413	.474	.228
T4	.276	.292	.156	**.386**	.246	.236	.201	.033
T5	.252	.215	.156	**.385**	.173	.127	.220	.131
T6	.439	.410	.426	**.631**	.558	.360	.384	.200
T7	.435	.392	.384	**.542**	.470	.394	.412	.276
T8	.429	.386	.530	**.616**	.507	.457	.428	.263
T9	.275	.229	.310	**.446**	.225	.293	.207	.215
T10	.335	.338	.374	**.578**	.359	.355	.322	.319
T11	.323	.328	.278	**.647**	.422	.287	.413	.295
T12	.311	.210	.249	**.631**	.293	.291	.331	.264
T13	.265	.360	.478	**.509**	.343	.314	.380	.551
EH1	.450	.303	.415	.385	**.638**	.316	.408	.282
EH2	.396	.325	.394	.395	**.618**	.319	.335	.301
EH3	.413	.275	.506	.379	**.650**	.379	.374	.220
EH4	.387	.227	.521	.471	**.733**	.391	.460	.277
EH5	.291	.190	.321	.248	**.504**	.324	.321	.159
EH6	.382	.203	.369	.359	**.668**	.338	.332	.190
EH7	.287	.241	.258	.294	**.572**	.255	.249	.137

Table 5 Item-scale correlations for multitrait-scaling analysis of the QoLMEAL:

128 adolescent report (cont.)

	Hypothesized domains							
	PH	**DA**	**F**	**T**	**EH**	**S**	**SC**	**FI**
EH8	.379	.330	.357	.401	**.650**	.497	.438	.188
EH9	.455	.366	.430	.552	**.739**	.380	.472	.221
S1	.309	.304	.360	.327	.393	**.581**	.388	.265
S2	.343	.336	.368	.290	.380	**.540**	.348	.234
S3	.114	.191	.202	.216	.301	**.426**	.299	.181
S4	.291	.215	.269	.302	***.414***	**.411**	.315	.119
S5	.259	.321	.382	.286	.316	**.456**	.232	.282
S6	.155	.223	.297	.280	.257	**.571**	.260	.236
S7	.399	.375	.330	.440	.463	**.706**	.335	.171
S8	.267	.270	.291	.319	.381	**.604**	.486	.105
S9	.368	.313	.348	.346	.361	**.737**	.495	.163
S10	.464	.389	.357	.395	.352	**.590**	.365	.181
SC1	.286	.296	.260	.362	.398	.296	**.501**	.261
SC2	.325	.317	.234	.448	.373	.331	**.574**	.189
SC3	.449	.354	.274	.550	.419	.408	**.649**	.227
SC4	.347	.292	.292	.397	.422	.507	**.578**	.185
SC5	.274	.247	.343	.400	.305	.359	**.640**	.149
SC6	.256	.252	.228	.329	.283	.357	**.631**	.176
SC7	.420	.428	.317	.401	.399	.547	**.586**	.226
FI1	.130	.171	.217	.142	.171	.101	.150	**.711**
FI2	.304	.343	.372	.391	.327	.294	.348	**.853**
FI3	.334	.428	.372	.331	.297	.233	.279	**.912**

PH, Physical health; DA, Daily activity; F, Family; T, Treatment; EH, Emotional health; S, Social; SC, Schooling; FI, Finances

Table 6 Item-scale correlations for multitrait-scaling analysis of the QoLMEAL:

123 parent report

	Hypothesized domains							
	PH	DA	F	T	EH	S	SC	FI
PH1	**.671**	.199	.179	.229	.278	.253	.265	.105
PH2	**.673**	.282	.243	.228	.355	.182	.332	.186
PH3	**.544**	.312	.191	.070	.175	.192	.193	.151
PH4	**.751**	.381	.273	.274	.347	.344	.269	.173
PH5	**.697**	.295	.231	.193	.275	.284	.325	.081
PH6	**.710**	.285	.331	.354	.402	.296	.335	.080
PH7	**.739**	.333	.248	.347	.420	.362	.240	.057
PH8	**.716**	.351	.249	.325	.434	.277	.352	.188
PH9	**.624**	.440	.297	.286	.357	.451	.377	.037
PH10	**.459**	.397	.155	.123	.170	.272	.279	.079
DA1	.144	**.359**	.178	.086	.145	.187	.185	.028
DA2	.319	**.719**	.295	.199	.255	.436	.316	.121
DA3	.336	**.835**	.352	.307	.276	.444	.345	.229
DA4	.173	**.379**	.233	.293	.201	.338	.162	.020
DA5	.164	**.206**	.109	***.211***	.192	.181	.172	-.016
DA6	.201	**.312**	.107	.204	.293	.252	.294	.127
DA7	.166	**.525**	.128	.279	.262	.392	.338	.275
DA8	.247	**.452**	.245	.329	.329	.438	.319	.219
DA9	.432	**.769**	.422	.347	.346	.475	.369	.295
DA10	***.419***	**.413**	.318	.312	.388	.326	.345	.047
F1	.176	.251	**.755**	.419	.417	.315	.296	.374
F2	.321	.343	**.847**	.583	.570	.477	.360	.221
F3	.249	.248	**.637**	.426	.454	.272	.384	.008
F4	.182	.249	**.563**	.264	.300	.260	.296	.229
T1	.177	.230	.307	**.454**	.279	.289	.200	.208
T2	.204	.230	.416	**.534**	.419	.389	.405	.249
T3	.395	.325	.469	**.674**	.401	.374	.433	.245
T4	.223	.096	.170	**.436**	.260	.187	.163	-.035
T5	.036	.043	.109	**.513**	.215	.101	.203	.056
T6	.328	.192	.407	**.643**	.507	.340	.366	.146
T7	.187	.355	.373	**.667**	.459	.494	.486	.035
T8	.085	.225	.361	**.666**	.429	.375	.389	.105
T9	.164	.166	.196	**.442**	.307	.186	.202	.113
T10	.167	.083	.394	**.562**	.353	.204	.356	.102
T11	.286	.073	.376	**.615**	.434	.258	.338	.068
T12	.156	.097	.335	**.694**	.499	.328	.377	.291
T13	.199	.345	.431	**.509**	***.544***	.414	.337	.441
EH1	.317	.374	.531	.582	**.777**	.581	.573	.337
EH2	.421	.297	.491	.479	**.684**	.506	.546	.271
EH3	.198	.228	.343	.364	**.596**	.400	.390	.299
EH4	.238	.220	.467	.475	**.653**	.477	.412	.097
EH5	.464	.278	.453	.442	**.685**	.406	.414	.190
EH6	.269	.214	.437	.440	**.700**	.327	.396	.137
EH7	.220	.143	.276	.432	**.535**	.337	.331	.168

Table 6 Item-scale correlations for multitrait-scaling analysis of the QoLMEAL: *123 parent report* (cont.)

	Hypothesized domains							
	PH	DA	F	T	EH	S	SC	FI
EH8	.313	.126	.317	.524	**.657**	.374	.406	.054
EH9	.252	.338	.414	.528	**.745**	.451	.450	.108
S1	.271	.337	.309	.367	.472	**.589**	.425	.162
S2	.214	.301	.330	.396	***.499***	**.481**	.403	.204
S3	.262	.343	.362	.482	.496	**.593**	.383	.225
S4	.156	.314	.129	***.371***	.303	**.365**	.235	.141
S5	.259	.346	.241	.371	.448	**.539**	.449	.247
S6	.216	.251	.294	.355	.472	**.628**	.379	.295
S7	.303	.325	.381	.392	.387	**.744**	.445	.177
S8	.310	.398	.375	.379	.431	**.744**	.497	.152
S9	.231	.380	.347	.360	.492	**.798**	.465	.098
S10	.217	.392	.391	.426	.419	**.720**	.477	.249
SC1	.148	.249	.305	.490	.476	.450	**.563**	.323
SC2	.297	.334	.306	.412	.497	.479	**.693**	.219
SC3	.317	.288	.426	.511	.606	.528	**.733**	.235
SC4	.162	.142	.176	.199	.318	.362	**.394**	.221
SC5	.363	.427	.318	.382	.468	.479	**.727**	.134
SC6	.291	.343	.291	.321	.353	.374	**.651**	.189
SC7	.158	.190	.250	.408	.424	.344	**.569**	.207
FI1	.087	.226	.251	.207	.219	.122	.251	**.809**
FI2	.183	.276	.304	.278	.299	.262	.381	**.828**
FI3	.136	.215	.241	.224	.267	.184	.275	**.883**

PH, Physical health; DA, Daily activity; F, Family; T, Treatment; EH, Emotional health; S, Social; SC, Schooling; FI, Finances

Table 7 Item scaling tests – convergent and discriminant validity for the QoLMEAL: *128 adolescent report and 123 parent report.*

Domains	No. of items per domain	Convergent validity (range of correlations)	Discriminant validity (range of correlations)	Scaling success	Homogeneity (average inter-item correlation)
Self-report					
PH	10	0.39-0.74	0.10-0.51	70/70	0.34
DA	10	0.15-0.80	(-0.02)-0.51	69/70	0.22
F	4	0.56-0.85	0.09-0.58	28/28	0.35
T	13	0.39-0.65	0.03-0.56	91/91	0.35
EH	9	0.50-0.74	0.14-0.55	63/63	0.41
S	10	0.41-0.74	0.11-0.49	69/70	0.37
SC	7	0.50-0.65	0.15-0.55	49/49	0.30
FI	3	0.71-0.91	0.10-0.43	21/21	0.56
Proxy-report					
PH	10	0.46-0.75	0.04-0.45	70/70	0.43
DA	10	0.21-0.84	(-0.02)-0.48	68/70	0.36
F	4	0.56-0.85	0.01-0.58	28/28	0.40
T	13	0.44-0.69	(-0.04)-0.54	90/91	0.28
EH	9	0.54-0.78	0.05-0.58	63/63	0.40
S	10	0.37-0.79	0.09-0.49	68/70	0.39
SC	7	0.39-0.73	0.13-0.61	49/49	0.46
FI	3	0.81-0.88	0.09-0.38	21/21	0.58

PH, Physical health; DA, Daily activity; F, Family; T, Treatment; EH, Emotional health; S, Social; SC, Schooling; FI, Finances; Scaling success, number of convergent correlations significantly higher then discriminant correlations / total number of correlations.

Scale-level analysis

Table 8 displays the value of Cronbach's alpha for the adolescent self-report and parent proxy-report scales. For the overall self-report scale, Cronbach's alpha was

0.94. The item reduction did not make any changes in the internal consistency. For physical health domain (10 questions), Cronbach's alpha was 0.84; for daily activity domain (10 questions), it was 0.74; for family domain (4 questions), it was 0.68; for treatment domain (13 questions), it was 0.87; for emotional health domain (9 questions), it was 0.86; for social domain (10 questions) it was 0.85; for schooling domain (7 questions), it was 0.75; and for finance domain (3 questions) it was 0.79. The values of Cronbach's alpha for the proxy-report scales were close to the values in the self-report scales.

Table 8 Internal consistency reliability for the QoLMEAL:
128 adolescent report and 123 parent report.

Domains (no. of items in domain)	Cronbach's α	
	Self-report	*Proxy-report*
- All domains (66)	0.94	0.95
- Physical health (10)	0.84	0.88
- Daily activity (10)	0.74	0.85
- Family (4)	0.68	0.73
- Treatment (13)	0.87	0.83
- Emotional health (9)	0.86	0.86
- Social (10)	0.85	0.86
- Schooling (7)	0.75	0.85
- Finances (3)	0.79	0.81

Table 9 displays the results of inter-scale Spearman rank correlation coefficients for adolescent self-report and parent proxy-report. Within the self-report, most domains were moderately to strongly inter-correlated (r, 0.31–0.63), except a pair of social and finance domain (r=0.27). Most self-report domains were moderately correlated with the parent proxy-report domains (r, 0.33-0.58), except between the daily activity domains (r=0.29). The Overall self-report scale was strongly correlated with the parent proxy-report scale (r=0.62).

Table 9 Multitrait-multimethod correlation matrix for patient self-report and parent proxy-report

Scale	Self report								Proxy report								
	DA	F	T	EH	S	SC	FI	All	PH	DA	F	T	EH	S	SC	FI	All
Self-report																	
- **PH**	.533†	.535†	.572†	.568†	.482†	.525†	.343†	.751†	**.580†**	.289†	.320†	.248†	.392†	.352†	.265†	.123	.423†
- **DA**		.376†	.507†	.404†	.499†	.465†	.424†	.634†	.338†	**.290†**	.244†	.236†	.312†	.345†	.267†	.204†	.413†
- **F**			.572†	.613†	.506†	.442†	.402†	.703†	.342†	.149	**.434†**	.206†	.266†	.248†	.217†	.217†	.419†
- **T**				.594†	.566†	.627†	.371†	.818†	.421†	.214†	.373†	**.352†**	.291†	.304†	.157	.154	.429†
- **EH**					.566†	.560†	.341†	.821†	.431†	.314†	.369†	.255†	**.356†**	.347†	.200†	.095	.431†
- **S**						.634†	.271†	.740†	.289†	.296†	.326†	.280†	.328†	**.420†**	.305†	.127	.478†
- **SC**							.311†	.820†	.334†	.246†	.314†	.250†	.416†	.394†	**.333†**	.053	.449†
- **FI**								.478†	.208†	.163	.194†	.035	.184†	.193†	.217†	**.448†**	.243†
- **All**									.561†	.330†	.473†	.349†	.468†	.420†	.344†	.151†	.616†
Proxy-report																	
- **PH**										.442†	.397†	.366†	.470†	.364†	.411†	.173	.645†
- **DA**											.429†	.359†	.389†	.512†	.472†	.276†	.629†
- **F**												.619†	.635†	.494†	.470†	.316†	.796†
- **T**													.701†	.553†	.597†	.272†	.813†
- **EH**														.633†	.658†	.283†	.855†
- **S**															.600†	.213†	.753†
- **SC**																.333†	.782†
- **FI**																	.421†

† $p < 0.05$; PH, Physical health; DA, Daily activity; S, Social; T, Treatment; EH, Emotional health; F, Family; SC, Schooling; FI, Finances; All, all domains

Table 10 Factor analysis of the 66 items of the instrument (values below 0.4 are suppressed)

	Component																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
PH1									-.443						.448				
PH2																		.729	
PH3																			.570
PH4															.650				
PH5																			
PH6								.464						.406	.466				
PH7														.544	.415				
PH8												.400			.438				
PH9									-.747										
PH10														.876					
DA1						-.916													
DA2																	.759		
DA3																	.817		
DA4										.555									
DA5						-.888													
DA6										.892									
DA7						-.421				.406						-.530	.491		
DA8									-.833										
DA9																	.673		
DA10									-.544										.402
F1	.766			.417															
F2	.718																		
F3							-.748												
F4							-.757												

Table 10 Factor analysis of the 66 items of the instrument (values below 0.4 are suppressed) (cont.)

	Component																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
T1											-.640								
T2	.414				.488						-.521		.535						
T3								.404			-.645								
T4													.822						
T5													.614						
T6	.459		-.412																
T7								.407											
T8			-.528																
T9					.580	-.515													
T10					.851														
T11					.837														
T12					.706														
T13				.542															
EH1	.434						-.624					.426	.466						
EH2							-.673						.413						
EH3	.475						-.617					.463							
EH4			-.513				-.409					.410	.569						
EH5						-.447										-.467			
EH6			-.805																
EH7			-.861																
EH8			-.729																
EH9	.446		-.519																

Table 10 Factor analysis of the 66 items of the instrument (values below 0.4 are suppressed) (cont.)

	Component																		
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19
S1		.629														-.479			
S2		.471	-.442						-.432							-.600			
S3																-.804			
S4			-.487													-.662			
S5		.458								.461						-.421			
S6		.783																	
S7		.464						.435									.515		
S8		.417						.513											
S9	.413											.663							
S10								.433											
SC1								.800											
SC2								.856											
SC3								.741											
SC4			-.441									.415			.415				
SC5												.695							
SC6												.771							
SC7												.431				-.442	.525		
FI1				.790															
FI2				.850															
FI3				.795															
Eigen-values	15.05	3.86	3.46	2.94	2.67	2.41	2.25	2.20	1.95	1.82	1.77	1.52	1.43	1.38	1.26	1.22	1.21	1.12	1.12
% of variance	22.8	5.85	5.25	4.45	4.04	3.66	3.41	3.33	2.95	2.76	2.67	2.29	2.17	2.09	1.90	1.85	1.83	1.70	1.69

Extraction Method: Principal Component Analysis. Rotation Method: Oblimin with Kaiser Normalization.

Table 10 show the confirmatory factor analysis of the 66-item and nineteen factors model converged in 42 iterations, with a chi-square value of 4983.52 and 2145 degrees of freedom ($p < 0.001$) in Bartlett's test of sphericity.

Testing of known-groups validity

ECLAM was computed for 101 patients because the 27 remainders were incomplete data. Most missing items in ECLAM were in the serology part. ECLAM ranged from 0 to 7 (mean 1.1, SD 1.6) and SDI ranged from 0 to 2 (mean 0.4, SD 0.6). There was no correlation between the domains and SDI, and small correlation between the physical health, daily activity, treatment domains and ECLAM (r 0.22, 0.20, and 0.23, respectively).

Table 11 Correlation of the domains and disease activity as assessed by the ECLAM index and damage as assessed by the SDI*: *128 adolescent report.*

	ECLAM		SDI	
	Correlation coefficient	*P*	Correlation coefficient	*P*
Self-report				
- All domains	0.21	*0.055*	0.06	*0.508*
- Physical health	0.22	*0.027*	0.07	*0.469*
- Daily activity	0.20	*0.048*	0.14	*0.115*
- Family	0.01	*0.898*	-0.03	*0.753*
- Treatment	0.23	*0.026*	0.02	*0.865*
- Emotional health	0.01	*0.955*	-0.004	*0.966*
- Social	0.03	*0.802*	0.03	*0.711*
- Schooling	0.09	*0.379*	0.12	*0.169*
- Finances	0.07	*0.475*	0.14	*0.126*

* ECLAM, European consensus lupus activity measurement; SDI, Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index