SUPPLEMENTARY TABLES

Table S1. SF-36: Internal Consistency and Test–Retest Reliability in SLE

Reference	SF-36 Domain	Reliability	
		Internal Consistency Cronbach's alpha	Test-retest Reliability*
Baba et al. 2018 (1)	PF	0.87	0.79
	RP	0.85	0.76
	BP	0.86	0.78
	GH	0.87	0.84
	VT	0.86	0.75
	SF	0.85	0.73
	RE	0.86	0.54
	MH	0.89	0.77
Thumboo et al. 2000 (2)	PF	0.87	0.90
	RP	0.91	0.75
	BP	0.82	0.78
	GH	0.78	0.89
	VT	0.82	0.89
	SF	0.82	0.82
	RE	0.87	0.65
	MH	0.72	0.80
Thumboo et al. 1999 (3)	PF	0.92	0.78
	RP	0.94	0.67
	BP	0.96	0.79
	GH	0.84	0.88
	VT	0.87	0.72
	SF	0.90	0.70
	RE	0.91	0.71
	MH	0.84	0.83

Abbreviations: BP=bodily pain; GH=general health; MH=mental health; PF=physical function; RE=role emotional; RP=role physical; SF=social functioning; SLE=systemic lupus erythematosus; VT=vitality.

* Spearman's rank correlation

Table S2. SF-36: Convergent Validity in SLE: HRQOL Measures

Reference	SF-36 Domain	Comparable Measure/Domain	Correlation[a,b]
Nantes et al. 2018 (4)	PF	LupusQoL Physical health	r=0.77
	BP	LupusQoL Pain	r=0.75
	VT	LupusQoL Fatigue	r=0.83
	MH	LupusQoL Emotional Health	r=0.77
McElhone et al. 2007 (5)	PF	LupusQoL Physical health	r=0.82
	BP	LupusQoL Pain	r=0.76
	VT	LupusQoL Fatigue	r=0.66
	MH	LupusQoL Emotional Health	r=0.74
Yilmaz-Oner et al. 2016 (6)	PF	LupusQoL Physical health	r=0.69
	BP	LupusQoL Pain	r=0.62
	VT	LupusQoL Fatigue	r=0.63
	RE	LupusQoL Emotional Health	r=0.69
Garcia-Carrasco et al. 2012 (7)	PF	LupusQoL Physical Health	Rho[b]=0.79
	RE	LupusQoL Emotional Health	Rho[b]=0.61
	BP	LupusQoL Pain	Rho[b]=0.48
	VT	Lupus QoL Fatigue	Rho[b]=0.58
Wolfe et al. 2010 (8)	PCS	EQ-5D	r=0.72
	MCS	EQ-5D	r=0.49
	PCS	EQ-5D VAS	r=0.61
	MCS	EQ-5D VAS	r=0.37
Touma et al. 2011 (9)	PF	LupusQoL Physical Health	r=0.75
	RE	LupusQoL Emotional Health	r=0.62
	BP	LupusQoL Pain	r=0.76
	VT	LupusQoL Fatigue	r=0.75

Abbreviations: BP=bodily pain; GH=general health; HRQOL=health-related quality of life; MCS=mental component subscale; MH=mental health; PCS=physical component subscale; PF=physical function; RE=role emotional; RP=role physical; SF=social functioning; SF-36=36-Item Health Survey – Short Form; VAS=visual analogue scale; VT=vitality.

[a] Spearman's correlations (r)

[b] Pearson´s product moment correlation coefficient (rho)

Table S3. SF-36: Divergent Validity in SLE: Disease Severity and Damage Measures

Reference	SF-36 Domain	Comparable Measure/Domain	Correlation[a,b]
Baba et al. 2018 (1)	All domains	SLEDAI-2K	-0.06 to 0.08[b]
	All domains	SDI	-0.47 to -0.08[b*]
Touma et al. 2011 (9)	PF	SLEDAI-2K	r= 0.17 to -0.02
	RP		r=-0.002 to -0.12
	BP		r=-0.11 to -0.01
	GH		r=0.14 to 0.20
	VT		r=-0.10 to 0.06
	SF		r=-0.16 to -0.13
	RE		r=-0.16 to 0.02
	MH		r=-0.16 to -0.05
Wolfe et al. 2010 (8)	PCS	LDIQ	r=-0.434**
	MCS	LDIQ	r=-0.141**
	PCS	Comorbidity Index*	r=-0.372**
	MCS	Comorbidity Index*	r=-0.272**
Thumboo et al. 2000 (2)	PF	BILAG General	r= -0.19 to 0.07
	RP		r= -0.31 to 0.01
	BP		r= -0.13 to 0.17
	GH		r= -0.41 to 0.07
	VT		r= -0.28 to 0.13
	SF		r= -0.34 to 0.05
	RE		r= -0.27 to 0.13
	MH		r= -0.21 to 0.10
	PF	SDI	r= -0.35 to 0.03
	RP		r= -0.31 to 0.11
	BP		r= -0.33 to 0.17
	GH		r= -0.29 to 0.14
	VT		r= -0.17 to 0.16
	SF		r= -0.24 to 0.19
	RE		r= -0.14 to 0.16
	MH		r= -0.21 to 0.14
Thumboo et al. 1999 (3)	PF	BILAG General	r=-0.07
	RP		r=-0.36**
	BP		r=-0.35**
	GH		r=-0.16
	VT		r=-0.31**
	SF		r=-0.30**
	RE		r=-0.20**
	MH		r=-0.19**
	PF	SDI	r=-0.20**
	RP		r=-0.17
	BP		r=-0.02

Reference	SF-36 Domain	Comparable Measure/Domain	Correlation[a,b]
	GH		r= -0.10
	VT		r= -0.04
	SF		r= -0.08
	RE		r= -0.06
	MH		r= 0.04

Abbreviations: BILAG=British Isles Lupus Assessment Group; BP=bodily pain; GH=general health; MCS=mental component subscale; MH=mental health; PCS=physical component subscale; PF=physical function; RE=role emotional; RP=role physical; SF=social functioning; SF-36=36-Item Health Survey – Short Form; SDI= SLICC/ACR damage index; SLEDAI-2K=Systemic Lupus Erythematosus Disease Activity Index 2000; SLE=systemic lupus erythematosus; SLICC=Systemic Lupus International Collaborating Clinics; SDI=SLICC/ACR damage index; VAS=visual analogue scale; VT=vitality.

* Comorbidity was measured by a patient-reported composite comorbidity index (range 0–9) consisting of 11 present or past comorbid conditions including pulmonary disorders, myocardial infarction, other cardiovascular disorders, stroke, hypertension, diabetes, spine/hip/leg fracture, depression, gastrointestinal (GI) ulcer, other GI disorders, and cancer.

** Significant p values <0.05

[a] Spearman's correlations (r)

[b] Pearson´ s product moment correlation coefficient (rho)

Table S4. SF-36: Known-groups Validity in SLE

Reference	Anchor (Clinical Severity Measure)	SF-36 Domain	Findings		
			Improved (mean, CI)	Same/Worsened (mean, CI)	p-value
Hanly et al. 2011 (10)	Physician neuropsychiatric event questionnaire*	PF	5.34 ± 1.54	−6.71 ± 3.46	0.0001
		RP	6.77 ± 3.28	−3.69 ± 7.28	0.075
		BP	6.17 ± 1.75	−3.10 ± 3.90	0.0006
		GH	4.88 ± 1.29	−6.18 ± 2.90	<0.0001
		VT	5.77 ± 1.56	−4.53 ± 3.43	0.0001
		SF	7.50 ± 1.92	−5.67 ± 4.24	0.0001
		RE	10.58 ± 3.46	−11.06 ± 7.67	0.0010
		MH	6.52 ± 1.45	−6.68 ± 3.19	<0.0001

Abbreviations: BP=bodily pain; CI=confidence interval; GH=general health; MH=mental health; PF=physical function; SD=standard deviation; SF=social functioning; SF-36=36-Item Health Survey – Short Form; RE=role emotional; RP=role physical

*A physician-generated 7-point Likert scale for NP events comparing the change in NP status between the onset of the event and time of study assessment was available for each NP event (1=patient demise, 2=much worse, 3=worse, 4=no change, 5=improved, 6=much improved, 7=resolved).

Table S5. Minimum Clinically Important Differences for SF-36 in Patients with SLE

Reference	Criterion Measure	Estimate
Colangelo et al. 2009 (11)	Patient-reported overall health status anchor*: "How would you describe your overall status since your last visit?"– much better, somewhat better, about the same, somewhat worse, or much worse*. Those who self-rated as better or worse were considered the "minimally changed" subgroups	*Mean (95% confidence interval)* Much better: PCS=8.4(3.8,12.9) Much better: MCS=9.1 (4.0, 14.3) Somewhat Better: PCS=2.1 (0.4,3.8) Somewhat Better: MCS= 2.4 (-0.2, 5) Somewhat worse: PCS=-2.2 (-4.1, -0.3) Somewhat worse: MCS=-1.2 (-4.1,1.9) Much worse: PCS=-5.0 (-15.0,5.1) Much worse: MCS=0.7 (-12.1,13.5)
Strand et al. 2005 (12)	15-point global rating of change scale improvement by a score of 6: "a little better" and worsening by a score of 10: "a little worse"	For improvement: 6.7-11.4 points for domain scores and 3.4-4.9 for PCS For clinically important worsening: -14.7 to -1.7 points for domain scores and between -2.1 and -0.8 for MCS and PCS, respectively

Abbreviations: MCID=minimum clinically important difference; MCS=mental component subscale; PCS=physical component subscale; SF-36=36-Item Health Survey – Short Form.

Table S6. Minimum Important Differences (MID) for SF-36 in Patients with SLE

Reference	Criterion Measure	Estimate	
		For clinical improvement (2 or 3) *mean (95% confidence interval)*	For clinical deterioration (-3 or-2) *mean (95% confidence interval)*
		PF: 3.8 (1.8, 5.8)	PF: -2.4 (-4.3, -0.5)
		RP: 10.8 (4.3, 17.4)	RP: -11.1 (-17.8, -4.5)
		BP: 10.9 (8.0, 13.8)	BP: -6.7 (-9.4, -4.0)
McElhone et	Anchor-based global rating of	GH: 2.8 (1.2, 4.5)	GH: -2.0 (-3.4, -0.5)
al. 2016 (13)	change category	VT: 10.9 (7.5, 14.3)	VT: -3.5 (-5.5, -1.4)
		SF: 9.6 (5.4, 13.8)	SF: -4.2 (-8.8, 0.3)
		RE: 10.2 (2.4, 18.0)	RE: -10.4 (-18.1, -2.7)
		MH: 7.5 (5.3, 9.8)	MH: -5.1 (-7.1, -3.2)
		Minimally improved on Likert scale Mean (SD)	Minimally worse on Likert scale Mean (SD)
		PF: 1.9 (11.9)	PF: -4.9 (17)
		RP: 11.3 (34.2)	RP: -15.6 (37.1)
Devilliers et al. 2015 (14)	MID was estimated as the mean change in SF-36 observed in the minimally improved and the minimally worse Likert categories	BP: 10.8 (19.9) GH: 3.3 (15.6) VT: 2.0 (18.8) SF: 8.5 (25.6)	BP: -12.8 (22.3) GH: -7.8 (12.9) VT: -4.4 (13.4) SF: -7.7 (21.8)
		RE: 7.8 (43.0)	RE: -11.8 (39.8)
		MH: 3.7 (19.4)	MH: -7.1 (17.3)

Abbreviations: MID=minimum important difference; MCS=mental component subscale; PCS=physical component subscale; SF-36=36-Item Health Survey – Short Form; SLE=systemic lupus erythematosus.

Table S7. LupusQoL: Internal Consistency and Test-Retest Reliability in SLE

Reference	LupusQoL Domain	Reliability	
		Internal Consistency Cronbach's alpha	Test–retest ICC (95% CI)
Meseguer et al. 2017 (15)	All	Ranged from 0.88 to 0.95	
Anindito et al. 2016 (16)	PH	0.87	0.89
	PA	0.86	0.80
	PL	0.87	0.75
	IR	0.89	0.74
	BU	0.89	0.84
	EH	0.86	0.94
	BI	0.88	0.95
	FA	0.87	0.91
Jolly et al. 2010 (17)	PH	0.93	0.92
	PA	0.93	0.88
	PL	0.93	0.92
	IR	0.91	0.88
	BU	0.92	0.83
	EH	0.94	0.84
	BI	0.89	0.81
	FA	0.85	0.68
McElhone et al. 2007 (5)	PH		0.93 (0.87, 0.97)
	PA		0.85 (0.77, 0.90)
	PL		0.86 (0.77, 0.92)
	IR		0.87 (0.73, 0.94)
	BU		0.76 (0.64, 0.85)
	EH		0.85 (0.74, 0.92)
	BI		0.80 (0.65, 0.89)
	FA		0.72 (0.50, 0.85)

Abbreviations: BI=body image; BU=burden; EH=emotional health; FA=fatigue; ICC=intraclass correlation coefficient; IR=Intimate relationships; LupusQoL=Lupus Quality of Life; PA=pain; PH=physical health; PL=planning; SLE=systemic lupus erythematosus; 95% CI=95% confidence interval.

Table S8. LupusQoL: Construct Validity in SLE

Reference	LupusQol Domain	Comparable Domains	Correlation
Meseguer et al. 2017 (15)	PH	SLAQ symptom scale	r= -0.72
	PA	SLAQ symptom scale	r= -0.76
	FA	SLAQ symptom scale	r= -0.70
	PH	EQ-5D analogic scale	r=0.76
	PA	EQ-5D analogic scale	r=0.80
	PL	EQ-5D analogic scale	r=0.76
Nantes et al. 2018 (4)	PH	SF-36 Physical Functioning	r=0.77
	PA	SF-36 Bodily Pain	r=0.75
	EH	SF-36 Mental Health	r=0.77
	FA	SF-36 Vitality	r=0.83
Anindito et al. 2016 (16)	PH	SF-36 Physical Functioning	r=0.45
	PA	SF-36 Bodily Pain	r=0.38
	EH	SF-36 Mental Health	r=0.64
	FA	SF-36 Vitality	r=0.49
Touma et al. 2011 (9)	PH	SF-36 Physical Functioning	r=0.75
	PA	SF-36 Bodily Pain	r=0.76
	EH	SF-36 Role Emotional	r=0.62
	FA	Sf-36 Vitality	r=0.75
Jolly et al. 2010 (17)	PH	SF-36 Physical Functioning	r=0.73
	PA	SF-36 Bodily Pain	r=0.66
	EH	SF-36 Mental Health	r=0.72
	FA	SF-36 Vitality	r=0.70
	PL	SF-36 Physical Functioning	r=0.63
	BU	SF-36 Social Functioning	r=0.54
	PH	EQ-5D Usual Activities	r= -0.64
	PA	EQ-5D Pain	r= -0.50
	EH	EQ-5D Anxiety/Depression	r= -0.68
	PL	EQ-5D Usual Activities	r= -0.50
McElhone et al. 2007 (5)	PH	SF-36 Physical Functioning	r=0.71
	PA	SF-36 Bodily Pain	r=0.76
	MH	SF-36 Mental Health	r=0.79
	FA	SF-36 Vitality	r=0.72

Abbreviations: BU=burden to others; EH=emotional health; FA=fatigue; LupusQoL=Lupus Quality of Life; MH=mental health; PA=pain; PH=physical health; PL=planning; SF-36=36-Item Health Survey – Short Form; SLAQ=Systemic Lupus Activity Questionnaire; SLE=systemic lupus erythematosus.

Table S9. LupusQoL: Known-groups Validity in SLE

Reference	LupusQoL Domain	Anchor (Clinical Severity Measure)	Findings			
			Improved (mean, SD)		Same/Worsened (mean, SD)	p-value
Touma et al. 2011 (9)	PH	SLEDAI-2K	71.9 ± 26.0		62.2 ± 24.3	0.17
	PA		76.2 ± 26.1		69.1 ± 29.2	0.36
	PL		78.6 ± 28.5		73.8 ± 29.2	0.52
	IR		81.3 ± 21.4		56.3 ± 37.7	0.01
	BU		64.5 ± 28.1		55.6 ± 26.6	0.25
	EH		77.8 ± 18.9		71.6 ± 25.0	0.34
	BI		72.2 ± 21.8		66.0 ± 29.5	0.41
	FA		64.7 ± 18.9		61.7 ± 26.8	0.67
McElhone et al. 2007 (5)			D/E/C in all systems	B in 1 system	B in ≥ 2 systems	A in any system
	PH	BILAG Index	65.89 ± 24.59	56.57 ± 25.40	55.00 ± 29.56	53.62 ± 29.76
	PA		68.43 ± 26.53	61.26 ± 25.13	59.33 ± 30.67	55.70 ± 30.81
	PL		71.68 ± 27.67	64.01 ± 28.56	58.16 ± 32.67	63.82 ± 28.47
	IR		67.06 ± 29.06	54.63 ± 36.27	60.80 ± 34.16	57.89 ± 32.33
	BU		64.72 ± 27.02	57.80 ± 28.35	52.48 ± 25.65	47.81 ± 32.26
	EH		76.96 ± 19.67	69.06 ± 21.73	72.25 ± 19.02	66.01 ± 22.10
	BI		77.57 ± 23.34	68.31 ± 27.70	65.97 ± 25.72	70.53 ± 25.22
	FA		55.64 ± 24.45	49.31 ± 24.48	47.30 ± 23.26	53.62 ± 26.46
			SDI = 0	SDI ≥ 1	P (95% CI)	
	PH	SDI	64.41 ± 29.97	52.74 ± 26.36	<0.002 (4.43, 20.48)	
	PA		67.55 ± 26.18	56.83 ± 28.44	<0.02 (1.34, 17.81)	
	PL		69.87 ± 28.41	60.51 ± 30.16	<0.02 (1.64, 19.32)	
	IR		64.63 ± 32.36	54.65 ± 33.70	<0.01 (2.96, 23.70)	
	BU		62.04 ± 27.65	55.78 ± 27.82	<0.04 (0.61, 17.59)	
	EH		73.54 ± 20.93	72.35 ± 20.31	NS (-3.70, 9.06)	
	BI		73.35 ± 25.19	70.31 ± 26.17	NS (-5.69, 9.91)	
	FA		53.83 ± 23.85	49.09 ± 25.26	NS (-2.51, 12.40)	

Abbreviations: BI=body image; BILAG=British Isles Lupus Assessment Group; BU=burden; EH=emotional health; FA=fatigue; IR=intimate relationships; LupusQoL=Lupus Quality of Life; NS=not significant; PA=pain; PL=planning; PH=physical health; SD=standard deviation; SDI= SLICC/ACR damage index; SF-36=36-Item Health Survey – Short Form; SLE=systemic lupus erythematosus; SLEDAI-2K=Systemic Lupus Erythematosus Disease Activity Index 2000; 95% CI=95% confidence interval.

Table S10. LupusQoL: Minimum Clinically Important Difference in SLE

Reference	MCID Calculated in Relation to	Method	MCID Estimate	
			Improvement	**Deterioration**
McElhone et al. 2016 (13)	Patient-completed GRC, ranging from 7 (a very great deal better) to -7 (a very great deal worse) with 0 indicating no change	MCIDs estimated using an anchor-based approach as mean changes in LupusQoL domains when minimal change (Deterioration= -3 or -2 points; Improvement =2 or 3 points) was reported on the GRC	PH=4.0 PA=6.8 PL=3.8 IR=7.1 BU=7.3 EH=4.7 BI=3.5 FA=6.6	PH=-3.4 PA=-4.7 PL=-4.0 IR=-8.7 BU=-5.0 EH=-3.7 BI=-2.4 FA=-3.2
Devilliers et al. 2015 (14)			**Minimally Improved**	**Minimally Worse**
	7-point Likert scale describing change in lupus health status over 3 months	MCID determined as the mean change in LupusQoL domains observed in the minimally improved and the minimally worse Likert categories	PH=3.4 PA=8.5 PL=6.5 IR=9.2 BU=5.3 EH=3.4 BI=1.1 FA=3.9	PH=-3.6 PA=-2.6 PL=-5.0 IR=-2.4 BU=-2.2 EH=-6.4 BI=-4.9 FA=-0.5

Abbreviations: GRC=Global Rating of Change; LupusQoL=Lupus Quality of Life; MCID=minimum clinically important difference; SD=standard deviation; SEM=standard error of the mean; SLE=systemic lupus erythematosus.

Table S11. FACIT-F: Construct Validity in SLE

Reference	Comparable Instrument	Correlation	
		Baseline[a]	Week 52
Strand et al. 2013 (48)	SF-36 Vitality		0.70[a]
Lai et al. 2011 (18)	SF-36 PCS	0.59	0.84[b]
	SF-36 MCS	0.52[b]	0.69[b]
	SF-36 VT	0.68[b]	0.87[b]
	BILAG Total	-0.26[b]	-0.25[b]
	Pain intensity	-0.60[b]	-0.72[b]
	Pain interference	-0.72[b]	-0.82[b]
	Patient Global Assessment	-0.58[b]	-0.76[b]
	Physician Global Assessment	-0.09[b]	-0.25[b]
Goligher et al. 2008 (19)	SLAQ	0.59[a]	
	Patient Global Assessment	0.49[a]	

Abbreviations: BILAG=British Isles Lupus Assessment Group; FACIT-F=Functional Assessment of Chronic Illness Therapy-Fatigue; MCS=mental component subscale; PCS=physical component subscale; SF-36=36-Item Health Survey – Short Form; SLAQ=Systemic Lupus Activity Questionnaire; SLE=systemic lupus erythematosus; VT=vitality.

[a] Pearson correlations

[b] Spearman correlations

Table S12. FACIT-F: Known-Groups Validity in SLE

Reference	Anchor (Clinical Severity Measure)	Findings				
		C/D/E (mean, SD)	B (mean, SD)	A (mean, SD)	p-value	Effect Size
Lai et al. 2011 (18)	BILAG Musculoskeletal, Baseline	25.1 (13.4)	18.9 (11.1)	15.7 (9.7)	<0.001	**C/D/E vs B**: 0.53; B vs A: 0.30
	BILAG General, Baseline	21.9 (12.0)	15.8 (9.7)	13.1 (9.0)	0.001	C/D/E vs B: 0.52 B vs A: 0.24
	BILAG Musculoskeletal, Week 12	26.8 (13.2)	21.4 (11.5)	18.8 (12.5)	0.003	C/D/E vs B: 0.42; B vs A: 0.22
		C/D/E (mean, SD)	**A/B (mean, SD)**		**p-value**	**Effect Size**
	BILAG General, Week 12	25.9 (13.0)	17.5 (10.3)		0.001	0.65

Abbreviations: BILAG=British Isles Lupus Assessment Group; FACIT-F=Functional Assessment of Chronic Illness Therapy-Fatigue; SD=standard deviation SLE=systemic lupus erythematosus.

Table S13. FACIT-F: Minimum Clinically Important Difference in SLE

Reference	MCID Calculated in Relation to	Method	MCID Estimate
Lai et al. 2011 (18)	Patient Global Assessment of Change, BILAG Musculoskeletal change, and BILAG General change	Combination of scores derived from responsiveness analyses, as well as distribution-based estimates using 1/3 SD, 1/2 SD, and SEM	3-7 points
Goligher et al. 2008 (19)	Six fatigue scales were used in addition to the FACIT-F, including the FSS, SF-36 VT, MAF, CFS, MFI, and an 11-point fatigues NRS. Conversations between pairs of participants followed, and then each participant rated their fatigue in relation to another participant on a 7- point scale	Estimated using a paired approach	Greater fatigue using normalized score =17.5; Less fatigue using normalized score = -5.3
		Estimated using an unpaired, linear regression approach	Original Scaling = -5.9 points

Abbreviations: BILAG=British Isles Lupus Assessment Group; CFS=Chalder Fatigue Scale; FACIT-F=Functional Assessment of Chronic Illness Therapy-Fatigue; FSS=Fatigue Severity Scale; MAF=Multidimensional Assessment of Fatigue; MCID=minimal clinically important different; MFI=Multidimensional Fatigue Inventory; NRS=numeric rating scale; SEM=standard error of the mean; SF-36 VT=SF-36 vitality; SLE=systemic lupus erythematosus.

Appendix Tables

Table A1. Basic Instrument Properties: SF-36, LupusQoL, and FACIT-F

Instrument Properties	SF-36	LupusQoL	FACIT-F
Initial language/ Country of development	English, UK	English, UK	English, US
Pathology/Disease	Generic instrument for all populations	SLE	Chronic Illness
Objective/General Concept	To measure HRQoL in adults	To measure disease-specific HRQoL in adult patients with SLE	To measure fatigue in people with chronic illnesses
Recall Period	Acute version = last week Chronic version = within the last 4 weeks	Past 4 weeks	Past 7 days
Domains (# of items)	36 items in 8 domains summarized into physical and mental component summary scores; domains = physical functioning, role limitations due to physical problems, bodily pain, general health perception, energy/vitality, social functioning, role limitations due to emotional problems, mental health	34 items in 8 domains (physical health, pain, planning, intimate relationship, burden to others, emotional health, body image, fatigue)	13 items related to fatigue
Response Options	Various response scales (1-5: excellent, very good, good, fair, poor; 1-5: much better now than one year ago, somewhat better now than one year ago, about the same, somewhat worse now than one year ago, much worse now than one year ago; 1-3: yes, limited a lot, yes, limited a little, no, not limited at all; Yes/No; 1-5: not at all, slightly, moderately, quite a bit, extremely; 1-6: none, very mild, mild, moderate, severe, very severe; 1-6: all of the time, most of the time, all good bit of the time, some of the time, a little of the time, none of the time; 1-5: all of the time, most of the time, some of the time, a little of the time, none of the time; 1-5: definitely true, mostly true, don't know, mostly false, definitely false)	5-point Likert response scale (0-4: all the time, most of the time, a good bit of the time, occasionally, never; also "not applicable" which does not receive a score)	4-point Likert response scale (very much, quite a bit, somewhat, a little bit and not at all) 0-4
Administration Mode	Paper and electronic versions available (suitable for self-administration or administration by a trained interviewer in person or by telephone)	Paper and electronic versions available via self-administration	Paper and electronic versions available via self-administration
Length of Administration	5-10 minutes	10 minutes or less	5-10 minutes
Scoring	PCS and MCS have always used z transformation and normative scoring of all 8 domains. Normative values = 50; SD=10 Version 2.0 scoring uses norm-based scoring algorithms for all 8 domains, with 50 defined as "normative". Domain scores without z transformation and normative scores range from 0 to 100 (higher scores indicate a better HRQoL) and are preferable when comparing across treatments or vs age and gender-matched norms	Mean raw domain is calculated by adding the response scores for each domain and then dividing the total by the number of items in the domain. The mean raw domain is then divided by 4 and multiplied by 100 for a transformed score. Scores range from 0-100 (worst HRQoL to best HRQoL)	Total score ranges from 0-52; high score represents less fatigue

Instrument Properties	SF-36	LupusQoL	FACIT-F
Version Assessed	US Version 2	Version 1	FACIT-F (Version 4)
Translations Available	Translated in more than 40 countries	Translated into 77 languages for use in 51 countries	Translated into over 45 languages
Reading and Comprehension Levels	6th-grade reading level	Not provided	4th grade reading level (9 or 10 years old)
Year Developed	Original development in 1988; standard form in 1990	Original development and validation study in 2007	Original development of questionnaires was in 1993
Previous Version History	Version 1.0	No previous versions	Versions 1, 2, and 3

Abbreviations: FACT=Functional Assessment of Cancer Therapy; FACIT-F=Functional Assessment of Chronic Illness Therapy-Fatigue; HRQoL=health-related quality of life; IQOLA=International Quality of life Assessment; LupusQoL=Lupus Quality of Life; MCS=mental component summary; PCS=physical component summary; PRO=patient-reported outcome; SD=standard deviation; SF-36=36-Item Health Survey – Short Form; SLE=systemic lupus erythematosus; UK=United Kingdom; US=United States.

Table A2. RCT Studies in SLE Including SF-36, LupusQoL, and FACIT-F

Citation and Study Location	Study Design, Population and Intervention Description	Study Objectives	Outcome Assessments	Key Clinical Findings	PRO Findings
Abrahão et al. 2016 (20) Brazil	Single-center parallel, blind RCT (n=63). Patients randomized to 3 groups: cardiovascular training (CT), resistance training (RT), and control. Study duration 12 weeks	To compare the efficacy of CT with RT in improving the HRQoL and physical function of patients with SLE	SF-36 BDI SLEDAI	No statistically significant difference in disease activity (SLEDAI) for patients in the intervention groups	Significant improvement in SF-36 scores for CT and RT groups (except VT in the RT group). CT patients reported higher SF-36 scores on RP and VT compared to RT and control groups. No statistically significant difference across the groups in depression
Arriens et al. 2015 (21) United States	Single-center, placebo-controlled trial (n=32). Patients randomized to fish oil supplementation or placebo. Study duration 6 months	To evaluate the effect of fish oil on clinical measures of fatigue, HRQoL, and disease activity.	RAND SF-36 FSS SLEDAI PGA	Change in SLEDAI scores were not statistically significant between groups	Significant improvement in PGA for treated patients vs placebo (p=0.015). Trend in improvement for the fish oil group for SF-36 VT and EF compared to the placebo group (p≤0.092)
Bostrom et al. 2016 (22) Sweden	Single-center, blind RCT (n=35). Patients randomized to intervention (physical activity program) or control. Study duration 1 year	To study the effects of physical activity program on aerobic capacity (primary outcome), physical activity, and HRQoL, (secondary outcomes)	Maximal oxygen update from bicycle ergometer test SF-36	V02 max increased independent of treatment group; no significant differences between the groups during the study period	Significant increase in SF-36 MF at 6 months in the I-group; difference was significantly different from that of the control group (p=0.03). No significant changes over time for other subscales
Cardiel et al. 2008 (23) North America and Europe	Multi-center, double-blind placebo-controlled RCT (n=317). Patients randomized to abetimus at 100 mg/ week or placebo. Study duration 22 months	To investigate whether treatment with abetimus delays renal flare in patients with lupus nephritis	SLEDAI SF-36	Abetimus did not significantly prolong time to renal flare or time to SLE flare	No significant improvements demonstrated within abetimus group or between the abetimus and placebo groups
Clowse et al. 2017 (24) Multiple countries	Two double-blind, placebo-controlled trials: EMBODY 1 (n=793) and EMBODY 2 (n=791). Patients randomized to receive placebo, epratuzumab 600 mg, or 1,200 mg. Study duration 48 weeks.	EMBODY 1 and EMBODY 2 trials, assessing the efficacy and safety of epratuzumab	BILAG-2004 SLEDAI-2K BICLA SF-36 LupusQoL FACIT-F	The primary endpoint was not met in EMBODY 1 or 2. No significant differences seen in the proportion of responders between treatment groups	Improvements were seen in all PROs, but no significant differences between groups

Citation and Study Location	Study Design, Population and Intervention Description	Study Objectives	Outcome Assessments	Key Clinical Findings	PRO Findings
Danowski et al. 2006 (25) United States	Single-center RCT (n=50). Subjects randomized to receive oral methylprednisolone with rapid tapering or triamcinolone 100 mg. Study duration 3 months	To investigate whether triamcinolone is superior to oral corticosteroids for mild/moderate flare in patients with lupus	SF-36 SELENA-SLEDAI	Both treatment groups did equally well. Triamcinolone may lead to a more rapid response in improvement of mild to moderate flare than methylprednisolone (69.5% vs 41.6%)	66.6% of patients in the oral methylprednisolone group and 73.9% in the triamcinolone group had some improvement in SF-36 at week 4
Dobkin et al. 2002 (26) Canada	Multi-center RCT (n=133). Patients randomized to brief supportive expressive group psychotherapy or a control group. Study duration 12 months	To evaluate the effect of group psychotherapy in reducing psychological distress, clinical outcomes, and healthcare costs, and improving HRQL	Symptom Checklist 90-revised SF-36 SLAM SLICC/ACR damage index HAQ	No clinically important differences between the groups on any outcome measures	No difference in SF-36 domains between the treatment and control group
Dussan et al. 2008 (27) United States	Parallel group RCT (n=47) comparing high-dose CYC (HD-CYC)) and monthly CYC (M-CYC). Study duration 2.5 years.	To compare HRQoL between HD-CYC and M-CYC	SF-36	Not applicable	At 6 months, HD-CYC group showed more improvement in SF-36 GH (p=0.026) and SF (p=0.0082) compared to M-CYC. At 18 months, HD-CYC showed more improvement in SF-36 RP (p=0.025). At 2.5 years, no significant differences between groups
Fiechtner & Montroy 2014 (28) Lansing, MI	Single-center, open-label RCT (n=10) evaluating Acthar Gel by subcutaneous injection. Study duration 28 days	To evaluate the efficacy of Acthar Gel for reducing active SLE	SELENA-SLEDAI PGA LupusQoL FACIT-F	The primary endpoint of SLEDAI-2K improvement was reached at all observation times ($p<0.05$)	All PROs significantly improved from baseline to 28 days: LupusQoL ($p\leq0.03$), FACIT-F ($p<0.01$), and Physician/Patient PGA (both $p<0.01$)
Fortin et al. 2008 (29) Canada	Multi-center, double-blind, placebo-controlled RCT (n=86). Patients randomized to methotrexate and placebo. Study duration 12 months	To assess the potential benefits of methotrexate SLE	SLAM-R SLEDAI SF-36	SLAM-R scores showed significant improvement in the mean scores (p=0.039). No significant differences with SLEDAI	No significant differences in SF-36 PCS and MCS scores between treatment groups
Furie et al. 2017 (30) Multiple countries	Phase 2b RCT (n=305). Patients randomized to IV placebo, anifrolumab 300 mg, or anifrolumab 1,000 mg. Study duration 48 weeks	To assess efficacy and safety of type I interferon (IFN) in moderate-to-severe SLE	SRI SF-36 FACIT-F	Primary endpoint met. INF patients achieved significantly greater responses in SRI compared to placebo ($p<0.05$)	Compared to placebo, greater proportions in 300 mg INF achieved >3-point FACIT score, and ≥ 3 SF-36 PCS and MCS scores. None of the comparisons were statistically significant

Citation and Study Location	Study Design, Population and Intervention Description	Study Objectives	Outcome Assessments	Key Clinical Findings	PRO Findings
Furie et al. 2011 (31) United States	Randomized, placebo-controlled Ph 3 trial (n=819). Patients randomized to 1 mg/kg belimumab, 10 mg/kg belimumab, or placebo. Study duration: 76 weeks.	To assess the efficacy/safety of the B lymphocyte stimulator inhibitor belimumab	SRI SELENA-SLEDAI SF-36	Significantly more SRI responders in 10-belimumab group than in placebo (p=0.017). No significant difference in 1-belimumab vs placebo. At 76 weeks no difference between groups	At week 24, no significant differences between groups in mean change in SF-36 PCS scores. At week 52, PCS score improvements were significant for belimumab groups compared placebo (*p*=0.012). At week 76, no significant group differences
Furie et al. 2008 (32) United States	Ph I, double-blind, randomized, dose-escalation study. Patients randomized to placebo or 1.0, 4.0, 10, or 20 mg/kg of belimumab. Study duration: 52 weeks.	To evaluate the safety, biologic activity, and pharmacokinetics of belimumab	SELENA-SLEDA Flare Index PGA SF-36	No significant differences between treatment groups in SELENA-SLEDAI, PGA, or flare rates	No significant differences in any SF-36 summary or domain scores
Gordon et al. 2008 (33) United States	Double-blind, placebo-controlled RTC (n=68). Patients randomized to testosterone and placebo). Study duration: 12 weeks.	To compare the efficacy and safety of testosterone and placebo patches in mild/moderate disease activity	SF-36 DSFI PGA SLAM-R SELENA-SLEDAI BILAG	T-group showed significant improvement in SLAM-R scores from baseline (change of 2.06±3.3, p=0.01)	Significant difference between treatment groups in mean change of score in “health transition” question of SF-36 (p=0.03). No other significant differences in SF-36. No significant differences in DSFI scores
Greco et al. 2008 (34) United States	Single-center, double-blind pilot RCT (n=24). Patients randomized to acupuncture, minimal needling, or usual care. Study duration: 5 weeks	To pilot test the safety and benefits of acupuncture to reduce pain and fatigue in patients with SLE	AIMS2-Pain MPI SF-36 FSS SLEDAI	40% of patients who received acupuncture reported ≥30% improvement in pain; no improvement in pain reported for usual care	SF-36 BP improved for acupuncture (mean change 3.0 (±9.5)), minimal needling (mean change 2.7 (±6.4)) and usual care (mean change 0.58 (±5.0)). SF-36 VT improved for acupuncture (mean change 1.6 (±8.0)), minimal needling (mean change 4.0 (±9.1)
Hartkamp et al. 2010 (35) The Netherlands	Single-center, double-blind placebo-controlled RCT (n=30). Participants with inactive SLE received DHEA or placebo. Study duration: 12 months.	To investigate the effects of DHEA on fatigue, mental well-being, and function in in inactive SLE	Multidimensional fatigue inventory Zung self-rating depressive scale SF-36 MCS & PCS	Not reported	In both groups, general fatigue (p<0.001) and SF-36 MCS) (p=0.04) significantly improved. No difference between DHEA and placebo groups for general fatigue and well-being and SF-36 PCS
Jolly et al. 2016 (36) France	Post hoc analysis from the PLUS study (7-month RCT) (n=166). Patients with SLE hydroxychloroquine (HCQ) levels 100 to 750 ng/mL randomized to no	To assess the association and predictive value of blood HCQ levels toward HRQoL in SLE	SF-36	Not reported	No significant correlations between HRQoL and HCQ; no differences when stratified by dose

Citation and Study Location	Study Design, Population and Intervention Description	Study Objectives	Outcome Assessments	Key Clinical Findings	PRO Findings
	daily dose change or increase in HCQ dose to meet target level				
Karlson et al. 2004 (37) United States	RTC (n=64). Patients and their partners randomized to a nurse-led patient/partner psychoeducation followed with monthly telephone calls or control group with a 45-min video presentation followed with monthly telephone calls. Study duration: 12 months	To evaluate psychoeducational program to improve patient self-efficacy and partner support to manage SLE	SF-36 MCS & PCS SLAQ & SLAM Fatigue Couples communication Self-efficacy	At 12 months, experimental group significantly improved in social support, self-efficacy, couple's communication, and fatigue compared to the controls (p<0.05)	SF-36 – MCS was higher in the experimental group compared to the control group (p=0.04). SF-36 PCS was higher in the experimental group compared to control, but not significantly different
Khamashta et al. 2016 (38)	Ph 2b RTC (n=431). Patients randomized to 3 doses of sifalimumab or placebo. Study duration: 52 weeks.	To assess efficacy, safety of sifalimumab in mod-severe SLE	SRI SLEDAI-2K PGA FACIT-F	Compared to placebo, a greater percentage of treatment group (all doses) met primary endpoint of an SRI-4	Percentage of patients with >3-point improvement in FACIT-F was not statistically different from placebo for the treatment groups
Kiani et al. 2013 (39) United States	Post hoc analysis of a 2-year RTC LAPS study (n=200). Patients in a trial randomized to atorvastatin and placebo. Study duration: 24 months	To identify predictors of HRQoL using SF-36 among patients with SLE	SELENA-SLEDAI PGA SF-36	Higher PGA associated with lower SF-36 PCS (p=0.033) and MCS (p=0.031)	No significant differences between treatment groups at 2 years. Presence of fibromyalgia associated with lower scores in SF-36 PF (p=0.0016), RP (p=0.015), BP (0.0006), GH (p=0.0052), VT (p=0.0086), SF (p=0.042), PCS (p=0.0002)
Merrill et al. 2010a (40) North America	Phase IIb randomized, double-blind, placebo-controlled trial (n=118). Patients randomized to abatacept and placebo (approx. 2:1 ratio). Study duration: 12 months	To evaluate abatacept in SLE and polyarthritis, discoid lesions, or pleuritis and/or pericarditis	BILAG SF-36 CES-D	After the steroid taper, 79.7% and 82.5% of patients in experimental and control groups had a flare. SAEs higher in the abatacept group (19.8% vs 6.8%)	Mean improvement from baseline to 12 months for experimental and control groups, respectively, was 6.24 and 2.32 for PCS and 5.81 and 3.57 for MCS. Improvements in PCS, MCS, fatigue, and sleep scores exceeded MCID for abatacept-treated patients
Merrill et al. 2010b (41) North America	EXPLORER RTC (n=257). Patients randomized at 2:1 ratio to IV rituximab or placebo. Study duration; 52 weeks	To test the efficacy and safety of rituximab vs placebo in patients with moderate-severe extrarenal SLE	BILAG SF-36	At week 52, no difference was noticed between major and partial clinical response rates in treatment groups. Also, there was no difference in disease activity between the groups	No significant difference between treatment groups in change in PCS score from baseline to week 52. Placebo (4.1 ± 17.0; 95% CI; 0.3–7.9) and rituximab 8.2 ± 22.8; 95% CI: 4.7–11.7 (p=0.1277)

Citation and Study Location	Study Design, Population and Intervention Description	Study Objectives	Outcome Assessments	Key Clinical Findings	PRO Findings
Navarra et al. 2011 (42) Latin America, Asia-Pacific, and eastern Europe	Phase III study (n=867). Patients randomized to 1 mg/kg belimumab, 10 mg/kg belimumab (n=290), or placebo. Study duration: 52 weeks.	To assess the efficacy and safety of fully human monoclonal antibody belimumab (BLyS-specific inhibitor) in patients with SLE	SRI SF-36	Significantly higher responder rate as assessed by SRI in 1 mg/kg (p=0.0129) and 10 mg/kg (p=0.0006) vs placebo	Both experimental groups had similar improvements in SF-36 at week 52 vs placebo (p=0.02 for both groups)
Navarrete-Navarrete et al. 2010 (43) Spain	Single-center RTC (n=34). Patients randomized to cognitive behavioral therapy and usual care. Study duration: 15 months.	To determine if cognitive behavioral therapy can improve QoL in patients with SLE	STAI BDI SF-36 Other stress measures	Not reported	SF-36 MCS improved significantly in cognitive behavioral group compared to usual care (p<0.035). PCS showed some improvement but was not statistically significant
Nordmark et al. 2005 (44) Sweden	Two-phase trial (n=37) with initial 6-month randomized, double-blind, placebo-controlled period, follow by 6 months of open-label DHEA treatment for all patients	To evaluate the efficacy of low dose DHEA on HRQoL in glucocorticoid treated SLE	SF-36 Hopkins Symptom Check List (HSCL) PGWBI McCoy Sex Scale Questionnaire	DHEA treatment increased serum levels of sulphated DHEA from subnormal to normal	DHEA group improved in SF-36 RE and HSCL total score (both p<0.05). During open treatment phase, former placebo group improved in SF-36 MH (p<0.05); improvement in HRQoL was not maintained for 12 months. Both groups improved on McCoy Sex Scale during DHEA treatment (p<0.05)
Petri et al. 2017 (45) North and Central America, Asia-Pacific	Ph 2 RTC (n=547). Patients were randomized to receive subcutaneous blisibimod in one of three dose levels (100 mg weekly (QW), 200 mg QW, or 200 mg every 4 weeks (Q4W)), or placebo. Study duration: 52 weeks	To evaluate the effects of blisibimod on fatigue and disease activity	SELENA-SLEDAI BILAG FACIT-F	Significant improvements in measures of disease activity	When compared to placebo, the effects of 100 mg or 200 mg blisibimod (QW) on fatigue were significant at various time points from week 8 to week 28 (all p<0.05) and surpassed the MCID. However, after week 28, evaluation on fatigue was confounded by lost to follow-up
Strand et al. 2015 (46) International	Phase II randomized, controlled trial	To determine efficacy of PF-04236921 in treating SLE	SRI-4 SF-36 FACIT-F EQ-5D	Not reported	SF-36 PCS scores showed statistically significant improvement over placebo group. PH, BP, GH, and VT approached significance and exceeded MCID. Improvements in FACIT-F and EQ-5D exceeded MCID
Strand et al. 2014b (47) International	Secondary analysis of 48-week, phase II/III RCT (ALLEVIATE). Patients randomized to usual care plus epratuzumab or placebo	To evaluate HRQoL and corticosteroid use in patients with mod-severe SLE	BILA PGA PtGA SF-36	No significant differences in BILAG at week 12	Baseline PCS scores were 2-3 SDs lower than age- and gender-matched norms, and MCS scores were ≤1 SD lower. At week 48, SF-36 scores approached or exceeded normative values in BP, SF, RE, MH, and VT

Citation and Study Location	Study Design, Population and Intervention Description	Study Objectives	Outcome Assessments	Key Clinical Findings	PRO Findings
Strand et al. 2013 (48) International	Secondary analysis of 2 P3 RCTs, BLISS-52 & BLISS-76 (52 weeks' duration; n=865 and 76 weeks' duration; n=819; respectively. Patients received placebo, or belimumab 1 or 10 mg/kg	To assess effects of belimumab plus standard treatment on HRQoL in SLE patients	SRI SF-36 FACIT-F EQ-5D	SRI rates at week 52 in BLISS-52 were significantly higher with belimumab 1 (p=0.01) and 10 (p<0.001) compared to placebo (44%)	In BLISS-52, mean changes from baseline to week 52 in PCS scores were significantly (p<0.05) greater with belimumab 1 and 10 vs placebo. In BLISS-76, significantly (p<0.05) greater improvements were seen with belimumab 1 in PCS and MCS scores. Significantly greater improvements in SF-36 PCS and VT and FACIT-F were evident at week 52 in both belimumab doses
Strand & Crawford 2005 (12)	Secondary analysis of two RCTs of LJP 394 (abetimus sodium). Ph 3 study, n=298 treated for 22 months. Phase 2/3 study, n=189 treated up to 18 months	To evaluate HRQoL in clinical trials of LJP 394 (abetimus sodium) for SLE	SF-36	Not reported (reported previously)	In Ph 3, responders improved in all SF-36 domains, with largest improvements in BP, VT, and GH (exceeded MCID). At 12 months, HRQoL was improved > MCID in ≥20% of responders in RP, BP, GH, VT
Strand et al. 2003 (49) United States and Europe	RCT (n=179) with patients randomized to LJP 394 (abetimus sodium) or placebo weekly for 16 weeks, followed by three 12-week treatment cycles of LJP 394 or placebo with 8-week intermissions. Study duration: 76 weeks	To evaluate efficacy of LJP 394 compared to placebo in SLE patients with prior renal involvement	SF-36	Trial was prematurely discontinued after interim analysis suggested that primary endpoint would not reach significance	SF-36 RE increased significantly in LJP group compared placebo (p=0.01), and meets MCID (11.3 points compared to 5.3)
Tench et al. 2003 (50) UK	RCT (n=93). Patients randomized to an exercise, relaxation, or a control group. Study duration: 12 weeks	To evaluate the efficacy of a graded aerobic exercise program in treating fatigue in patients with SLE	FSS PSQI SF-36 HADS SLAM SLICC/ACR damage index	49% of exercise group rated "much" or "very much" better compared 28% in the relaxation and 16%) in the control group (p=0.02). Fatigue improved significantly on one out of three measures after exercise therapy	There was a significant difference in the SF-36 VT between the groups, exercise mean 51 (SE=4), relaxation mean 41 (SE=4), control group mean 34 (SE=4)
Uppal et al. 2009 (51) Kuwait	Single-center, open-label pilot RCT (n=46). Patients randomized to infliximab (n=9) or standard care (n=18); n=19 healthy controls. Study duration: 6 months	To assess the safety and efficacy of infliximab in patients with active SLE.	SF-36 PtGA SLEDAI SLICC/ACR Damage index Fatigue (VAS)	Treatment group showed significantly greater improvement in (SLEDAI) (p=0.035).	Greater improvement in the SF-36 domains for the infliximab group compared to standard care, but not statistically significant

Citation and Study Location	Study Design, Population and Intervention Description	Study Objectives	Outcome Assessments	Key Clinical Findings	PRO Findings
Wallace et al. 2016a (52) International	Patients from a 12-week, phase IIb, EMBLEM study enrolled in open-label extension study. N=113 patients continued epratuzumab through end of open-label extension period	To assess the long-term safety of repeated courses of epratuzumab therapy in patients with moderate-severe lupus	BILAG SELENA-SLEDAI PGA/PtGA SF-36	TEAEs were reported in 192 patients (most common infections and infestations). Serious TEAEs were reported in 51 patients, and 14 patients had serious infections	Mean SF-36 PCS and MCS scores increased from screening to week 48,and were maintained through week 108. Change from EMBLEM trial baseline (prior to open-label extension) were clinically meaningful at all time points. At the last visit for each patient, 61.9% achieved change greater than MCID in PCS, and 44.1% in MCS
Wallace et al. 2016b (53) International	Ph 2, dose-ranging, randomized, placebo-controlled trial (n=183). Patients randomized to placebo, or one of three dosages of the interleukin 6. Study duration: 24 weeks	To evaluate the safety of an interleukin 6 monoclonal antibody for the treatment of SLE	SRI BICLA SF-36 EQ-5D FACIT-F	SRI response rates were not significant for any dose compared to placebo	Mean baseline SF-36 PCS and MCS were below norms. Trends toward improvements in most SF-36 domains, PCS, FACIT-F, an EQ-5D scores were reported with 10 mg or 50 mg vs placebo at week 24. All HRQoL changes from baseline with 10 mg exceeded MCIDs

Abbreviations: anti-dsDNA=anti-double-stranded deoxyribonucleic acid; BDI=Beck Depression Inventory; BICLA=BILAG-Based Composite Lupus Assessment; BILAG=British Isles Lupus Assessment Group; CB-CAP=cell-bound complement activation product; CI=confidence interval; CT=cardiovascular training; CYC=cyclophosphamide; DHEA=dehydroepiandrosterone; DSFI=Derogatis Sexual Functioning Inventory; FACIT-F=Functional Assessment of Chronic Illness Therapy-Fatigue; FSS=Fatigue Severity Scale; HADS=Hospital Anxiety and Depression Scale; HAQ=Health Assessment Questionnaire; HRQoL=health-related quality of life; HSCL=Hopkins Symptom Check List; IQOLA=International Quality of Life Assessment; IQR=interquartile ratio; LupusQoL=Lupus Quality of Life; MCID=minimal clinically important difference; MCS=mental component summary; PCS=physical component summary; PGA=Physician Global Assessment; PtGA=Patient Global Assessment; PRO=patient-reported outcome; PSQI=Pittsburgh Sleep Quality Index; QoL=quality of life; RCT=randomized controlled trial; RT=resistance training; SD=standard deviation; SELENA-SLEDAI=Safety of Estrogens in Systemic Lupus Erythematosus National Assessment – Systemic Lupus Erythematosus Disease Activity Index; SF-36=36-Item Health Survey – Short Form; SLAM-R=Systemic Lupus Activity Measure, Revised; SLAQ=Systemic Lupus Activity Questionnaire; SLEDAI=SLE Disease Activity Index; SLEDAI-2K=Systemic Lupus Erythematosus Disease Activity Index 2000; SLE=systemic lupus erythematosus; SLICC=Systemic Lupus International Collaborating Clinics; SRI=SLE Responder Index; TEAE=treatment-emergent adverse event; UK=United Kingdom; uPCR=Urine Protein to Creatine; US=United States; VO2=oxygen consumption.

Table A3. Summary of Longitudinal Observational Studies Including SF-36, LupusQoL, and FACIT-F

Citation and Study Location	Study Design Population and Interventions Description	Study Objectives	Outcome Assessments	Key Clinical Findings	PRO Findings
Buyon et al. 2016 (54) United States	Longitudinal study (n=36) among SLE patients with active disease and elevated CB-CAPs. Participants were evaluated monthly for 11 months	To evaluate relationship between CB-CAPs: EC4d, EC3d), anti-C1q, soluble complement C3/C4 and disease activity in SLE	SELENA-SLEDAI SF-36	Decrease in SELENA-SLEDAI scores were significantly associated with reduced EC4d and EC3d levels, reduced anti-C1q titres and increased serum complement C3/C4 ($p<0.05$)	Increases were observed in all domains of the SF-36. Reduced EC4d or EC3d significantly associated with improvements in 6/8 domains of the SF-36; PH and RE were not significantly associated with EC4d or EC3d
Goharifar et al. 2015 (55) Iran	Case control observation study (n=40) of SLE patients, n=21 fasting patients, and n=19 controls. Study duration: 3 months	To evaluate the effect of Ramadan fasting on SLE patients' disease activity, HRQoL, and lipid profile	SELENA-SLEDAI lipid profile SF-36	No significant differences in SELENA-SLEDAI scores between groups at any visit	Within group improvements for both groups statistically significant: SF-36 BP ($p=0.002$), SF ($p=0.09$), MH ($p=0<0.001$), RE ($p=0.016$), VT ($p=0.04$). No significant between-group differences

Abbreviations: BP=bodily pain; FACIT-Fatigue=Functional Assessment of Chronic Illness Therapy-Fatigue; HRQoL=health-related quality of life; LIT=lupus impact tracker; LupusQoL=Lupus Quality of Life; SELENA-SLEDAI=Safety of Estrogens in Systemic Lupus Erythematosus National Assessment – Systemic Lupus Erythematosus Disease Activity Index; SF=social functioning; SF-36=36-Item Health Survey – Short Form; SLE=systemic lupus erythematosus; SLEDAI=SLE Disease Activity Index.

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