






















Supplementary Materials: Effects of 12-week Aerobic Exercise on Arterial Stiffness, Inflammation, and Cardiorespiratory Fitness in Women with Systemic LUPUS Erythematosus: Non-Randomized Controlled Trial

Table S1. TREND Statement for improving the reporting of non-randomized experiments.

Paper Section/ Topic	Item No.	Descriptor	Reported?	
				Pg #
Title and Abstract				
Title and Abstract	1	Information on how unit were allocated to interventions		1
		Structured abstract recommended		1
		Information on target population or study sample		1
Introduction				
Background	2	Scientific background and explanation of rationale		1-2
		Theories used in designing behavioral interventions		2
Methods				
Participants	3	Eligibility criteria for participants, including criteria at different levels in recruitment/sampling plan (e.g., cities, clinics, subjects)		3
		Method of recruitment (e.g., referral, self-selection), including the sampling method if a systematic sampling plan was implemented		3
		Recruitment setting		3
		Settings and locations where the data were collected		3
Interventions	4	Details of the interventions intended for each study condition and how and when they were actually administered, specifically including:		3-5
		o Content: what was given?		3-4
		o Delivery method: how was the content given?		5
		o Unit of delivery: how were the subjects grouped during delivery?		5
		o Deliverer: who delivered the intervention?		5
		o Setting: where was the intervention delivered?		5
		o Exposure quantity and duration: how many sessions or episodes or events were intended to be delivered? How long were they intended to last?		3-5
		o Time span: how long was it intended to take to deliver the intervention to each unit?		4
o Activities to increase compliance or adherence (e.g., incentives)		5		
Objectives	5	Specific objectives and hypotheses		2
Outcomes	6	Clearly defined primary and secondary outcome measures		2, 5-6

Sample Size	7	Methods used to collect data and any methods used to enhance the quality of measurements		5-6
		Information on validated instruments such as psychometric and biometric properties		5-6
		How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules		6
Assignment Method	8	Unit of assignment (the unit being assigned to study condition, e.g., individual, group, community)		7
		Method used to assign units to study conditions, including details of any restriction (e.g., blocking, stratification, minimization)		7
		Inclusion of aspects employed to help minimize potential bias induced due to non-randomization (e.g., matching)		7
Blinding (masking)	9	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to study condition assignment; if so, statement regarding how the blinding was accomplished and how it was assessed.		7
Unit of Analysis	10	Description of the smallest unit that is being analyzed to assess intervention effects (e.g., individual, group, or community)		7
		If the unit of analysis differs from the unit of assignment, the analytical method used to account for this (e.g., adjusting the standard error estimates by the design effect or using multilevel analysis)		n/a
Statistical Methods	11	Statistical methods used to compare study groups for primary methods outcome(s), including complex methods of correlated data		7
		Statistical methods used for additional analyses, such as a subgroup analyses and adjusted analysis		7
		Methods for imputing missing data, if used		7
		Statistical software or programs used		7
Results				
Participant flow	12	Flow of participants through each stage of the study: enrollment, assignment, allocation, and intervention exposure, follow-up, analysis (a diagram is strongly recommended)		8
		o Enrollment: the numbers of participants screened for eligibility, found to be eligible or not eligible, declined to be enrolled, and enrolled in the study		8
		o Assignment: the numbers of participants assigned to a study condition		8
		o Allocation and intervention exposure: the number of participants assigned to each study condition and the number of participants who received each intervention		8
		o Follow-up: the number of participants who completed the follow-up or did not complete the follow-up (i.e., lost to follow-up), by study condition		8
		o Analysis: the number of participants included in or excluded from the main analysis, by study condition		8
Recruitment	13	Description of protocol deviations from study as planned, along with reasons		3, 5
		Dates defining the periods of recruitment and follow-up		3

Baseline Data	14	Baseline demographic and clinical characteristics of participants in each study condition	✓	7, 9
		Baseline characteristics for each study condition relevant to specific disease prevention research	✓	7, 9
		Baseline comparisons of those lost to follow-up and those retained, overall and by study condition	✓	-
		Comparison between study population at baseline and target population of interest	✓	7, 9
Baseline equivalence	15	Data on study group equivalence at baseline and statistical methods used to control for baseline differences	✓	7
Numbers analyzed	16	Number of participants (denominator) included in each analysis for each study condition, particularly when the denominators change for different outcomes; statement of the results in absolute numbers when feasible	✓	Tables 3, 4, S3, S4, Fig. 2
		Indication of whether the analysis strategy was “intention to treat” or, if not, description of how non-compliers were treated in the analyses	✓	7, Tables 3, 4, S3, S4, Fig. 1
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each estimation study condition, and the estimated effect size and a confidence interval to indicate the precision	✓	Tables 3, 4, S3, S4, Fig. 2
		Inclusion of null and negative findings	✓	10-17
		Inclusion of results from testing pre-specified causal pathways through which the intervention was intended to operate, if any		n/a
Ancillary analyses	18	Summary of other analyses performed, including subgroup or restricted analyses, indicating which are pre-specified or exploratory		n/a
Adverse events	19	Summary of all important adverse events or unintended effects in each study condition (including summary measures, effect size estimates, and confidence intervals)	✓	7
DISCUSSION				
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias, imprecision of measures, multiplicative analyses, and other limitations or weaknesses of the study	✓	12-13
		Discussion of results taking into account the mechanism by which the intervention was intended to work (causal pathways) or alternative mechanisms or explanations	✓	12-13
		Discussion of the success of and barriers to implementing the intervention, fidelity of implementation	✓	13
		Discussion of research, programmatic, or policy implications	✓	13
Generalizability	21	Generalizability (external validity) of the trial findings, taking into account the study population, the characteristics of the intervention, length of follow-up, incentives, compliance rates, specific sites/settings involved in the study, and other contextual issues	✓	13
Overall Evidence	22	General interpretation of the results in the context of current evidence and current theory	✓	12-13

Reference: Des Jarlais, D.C.; Lyles, C.; Crepaz, N.; The Trend Group (2004). Improving the reporting quality of nonrandomized evaluations of behavioral and public health interventions: The TREND statement. *Am. J. Public Health* 2004, 94, 361–366.

Table S2. CERT checklist from *the EJERCITALES Study* physical exercise program.

	Item	Checklist Item	Identification
WHAT: materials	1	Detailed description of the type of exercise equipment	<i>Page 3</i>
WHO: provider	2	Detailed description of the qualifications, expertise and/or training	<i>Page 5</i>
HOW: delivery	3	Describe whether exercises are performed individually or in a group	<i>Page 5</i>
	4	Describe whether exercises are supervised or unsupervised; how they are delivered	<i>Page 5</i>
	5	Detailed description of how adherence to exercise is measured and reported	<i>Page 5</i>
	6	Detailed description of motivation strategies	<i>Page 5</i>
	7 ^a	Detailed description of the decision rule (s) for determining exercise progression	<i>Page 5</i>
	7b	Detailed description of how the exercise program was progressed	<i>Page 5 and table 1</i>
	8	Detailed description of each exercise to enable replication	<i>Page 3, 5, and Table 1</i>
	9	Detailed description of any home programme component	<i>Page 5</i>
	10	Describe whether there are any non-exercise components	<i>Page 5</i>
	11	Describe the type and number of adverse events that occur during exercise	<i>Page 7 (results section)</i>
WHERE: location	12	Describe the setting in which the exercises are performed	<i>Page 5</i>
WHEN, HOW MUCH: dosage	13	Detailed description of the exercise intervention	<i>Page 5 and table 1</i>
TAILORING: what, how	14 ^a	Describe whether the exercises are generic (one size fits all) or tailored	<i>Page 5</i>
	14b	Detailed description of how exercises are tailored to the individual	<i>Page 5</i>
	15	Describe the decision rule for determining the starting level	<i>Page 5</i>
HOW WELL: planned, actual	16 ^a	Describe how adherence or fidelity is assessed/measured	<i>Page 5</i>
	16b	Describe the extent to which the intervention was delivered as planned	<i>Page 5</i>

Table S3. Per-protocol analyses assessing the effects of 12-week progressive aerobic exercise on arterial stiffness, inflammation, oxidative stress, and cardiorespiratory fitness in women with systemic lupus erythematosus (participants in the exercise group were included if attendance $\geq 90\%$).

Change from Baseline at Week 12	Intervention		Mean Difference (95%CI)	<i>p</i>
	Exercise (<i>n</i> = 18) Median (SE)	Control (<i>n</i> = 28) Median (SE)		
PWV, m/s	-0.26 (0.14)	-0.25 (0.11)	-0.010 (-0.38 to 0.36)	0.958
hsCRP, mg/L	-0.12 (0.58)	-0.183 (0.48)	0.064 (-1.50 to 1.62)	0.934
TNF- α , pg/mL	-4.15 (1.69)	-2.49 (1.41)	-1.65 (-6.28 to 2.97)	0.475
IL-6, pg/mL	-4.22 (1.13)	-5.64 (0.96)	1.41 (-1.77 to 4.59)	0.375
MPO, ng/mL	-29.30 (11.45)	-8.95 (9.56)	-20.35 (-51.25 to 10.54)	0.191
Cardiorespiratory fitness (Bruce), min	2.42 (0.50)	0.28 (0.41)	2.14 (0.75 to 3.54)	0.003

The analyses were adjusted for baseline values, resting heart rate and changes in self-reported physical activity during the study period. SE, standard error; CI, confidence interval; PWV, pulse wave velocity; hsCRP, high sensitivity C-reactive protein; TNF- α , tumor necrosis factor alpha; IL-6, interleukin-6; MPO, myeloperoxidase.

Table S4. Sensitivity analyses: Complete case analyses assessing the effects of 12-week progressive aerobic exercise on arterial stiffness, inflammation, oxidative stress, and cardiorespiratory fitness in women with systemic lupus erythematosus (only participants with valid data were included).

Change from Baseline at Week 12	Intervention		Mean Difference (95%CI)	<i>p</i>
	Exercise (<i>n</i> = 26) Median (SE)	Control (<i>n</i> = 28) Median (SE)		
PWV, m/s	-0.24 (0.12)	-0.21 (0.12)	-0.03 (-0.39 to 0.32)	0.838
hsCRP, mg/L	0.08 (0.61)	-0.17 (0.62)	0.25 (-1.52 to 2.03)	0.777
TNF- α , pg/mL	-3.51 (1.69)	-2.72 (1.73)	-0.79 (-5.73 to 4.15)	0.749
IL-6, pg/mL	-3.40 (0.90)	-5.24 (0.92)	1.84 (-0.830 to 4.51)	0.172
MPO, ng/mL	-16.61 (8.44)	-10.44 (8.85)	-6.18 (-30.90 to 18.55)	0.618
Cardiorespiratory fitness (Bruce), min	2.72 (0.38)	0.19 (0.39)	2.54 (1.39 to 3.68)	<0.001

The analyses were adjusted for baseline values, resting heart rate, and changes in self-reported physical activity during the study period. SE, standard error; CI, confidence interval; PWV, pulse wave velocity; hsCRP, high sensitivity C-reactive protein; TNF- α , tumor necrosis factor alpha; IL-6, interleukin-6; MPO, myeloperoxidase.

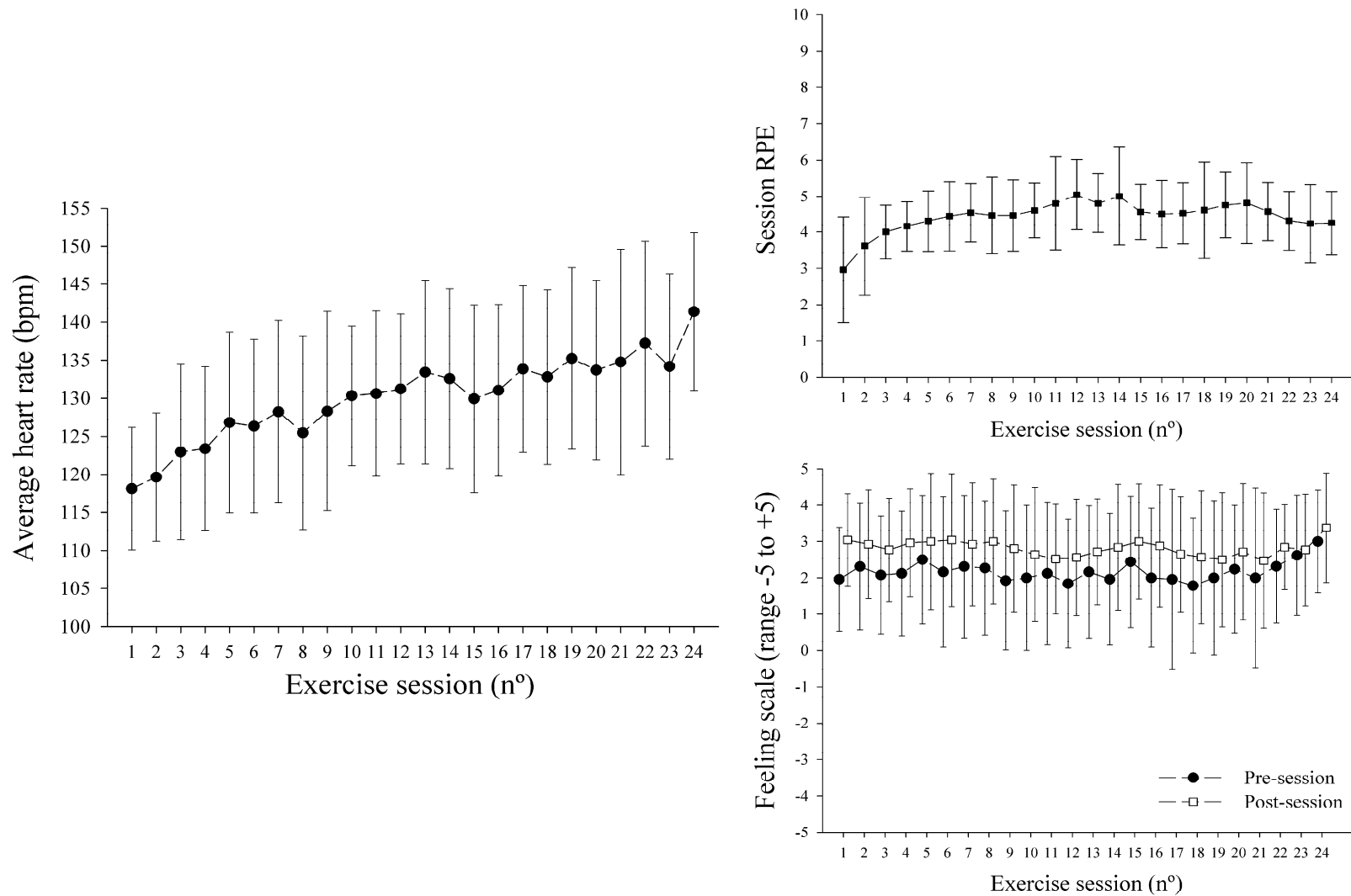


Figure S1. Summary of objective (i.e., heart rate) exercise intensity, session rating of perceived exertion (RPE), and (pre- and post-session) positive affect (feeling scale) during each session of the exercise program. Bpm, beats per minute.

Table S5. Between-group comparison of the change in traditional cardiovascular disease risk factors from baseline at week 12.

Change from Baseline at Week 12	Intervention		Mean Difference (95%CI)	<i>p</i>
	Exercise (<i>n</i> = 22) Median (SE)	Control (<i>n</i> = 28) Median (SE)		
BMI, kg/m ²	-0.37 (0.21)	-0.33 (0.19)	-0.05 (-0.64 to 0.54)	0.863
SBP, mm/Hg	-5.9 (2.4)	-5.7 (2.2)	-0.26 (-7.13 to 6.61)	0.939
DBP, mm/Hg	-2.6 (1.9)	-4.9 (1.8)	2.30 (-3.2 to 7.8)	0.403
MBP, mm/Hg	-4.1 (2.0)	-5.5 (1.8)	1.46 (-4.2 to 7.1)	0.605
Insuline, mg/dL	-0.58 (0.76)	-0.95 (0.68)	0.37 (-1.78 to 2.53)	0.729
HOMA-IR	0.07 (0.16)	-0.22 (0.15)	0.30 (-0.16 to 0.75)	0.197

BMI, body mass index; SBP, systolic blood pressure; DBP, distolic blood pressure; MBP, mean blood pressure; HOMA-IR, homeostasis model assessment of insulin resistance.