The effect of surface electromyography biofeedback on the activity of extensor and dorsiflexor muscles in elderly adults: a randomized trial

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Supplementary Table S1. CONSORT 2010 checklist of trial: Effect of surface electromyography biofeedback on the activity of extensor and dorsiflexor muscles in elderly adults: a randomized clinical trial. Ana Belén Gámez, Juan José Hernández Morante, José Luis Martínez Gil, Francisco Esparza, Carlos Manuel Martínez.

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	#1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	#2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	#3
	2b	Specific objectives or hypotheses	#4
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	#11
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	#11-12
	4b	Settings and locations where the data were collected	#11
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	#13-14
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	#13
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	#12
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	#11
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	#11
Allocation concealment	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	#11

mechanism			
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	#11
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	#15-16
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	#15-16
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	#5
	13b	For each group, losses and exclusions after randomisation, together with reasons	#5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	#11
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1 #23
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	#5-6
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	#5-6
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	#5-6
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	#10
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	#7-10
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	#7-10
Other information			
Registration	23	Registration number and name of trial registry	#11
Protocol	24	Where the full trial protocol can be accessed, if available	#11
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	#21

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Supplementary Table S2. Changes in average EMG activity in the hemiparetic and normal extremities. Between group difference represent estimated treatment differences (ETDs) and 95% CIs. Data are from the full analysis set (completers subjects). Data at baseline are mean ±s.d. Statistically significance values were determined through the ANCOVA analysis.

	BASELINE		Observed Mean ± SD change from baseline		Mean between group difference	Significance
	CONTROL (n=14)	sEMG-B (n=14)	CONTROL (n=14)	sEMG-B (n=14)	(control vs sEMG-B) 95% CI	(ANCOVA)
EMG activity hemiparetic upper limb	31.7 ± 14.2	45.8 ± 8.2	0.6 ± 10.3	22.6 ± 18.0	-22.0 (-33.4 - -10.6)	<0.001
EMG activity normal upper limb	62.5 ± 25.5	88.2 ± 40.0	8.4 ± 24.2	18.3 ± 15.8	-9.8 (-25.7 - 6.0)	0.104
EMG activity hemiparetic lower limb	29.8 ± 11.5	26.2 ± 14.6	8.1 ± 12.3	33.1 ± 17.0	-25.1 (-36.6 - -13.5)	<0.001
EMG activity normal lower limb	64.8± 27.7	62.9 ± 38.5	24.5 ± 22.2	33.5 ± 35.7	-9.0 (-32.1 - 14.1)	0.603

Supplementary Table S3. Changes in average EMG activity in the hemiparetic and normal extremities. Between group difference represent estimated treatment differences (ETDs) and 95% CIs. Data are from the full analysis set (completers subjects). Data at baseline are mean ±s.d. Statistically significance values were determined through the ANCOVA analysis.

	BASELINE		Observed Mean ± SD change from baseline		Mean between group difference	Significance
	CONTROL (n=14)	sEMG-B (n=14)	CONTROL (n=14)	sEMG-B (n=14)	(control vs sEMG-B) 95% CI	(ANCOVA)
Barthel	56 ± 15	52 ± 18	0.2 ± 0.8	3.9 ± 4.3	-3.7 (-6.1 - -1.3)	0.006
FUGL-MEYER_Upper limb	81 ± 10	97 ± 13	7.5±14.8	7.9±8.4	-0.4 (-9.7 - 9.0)	0.938
FUGL-MEYER_Lower limb	89 ± 19	154 ± 49	0.9±1.5	9.1±9.6	-8.2 (-13.5 - -2.9)	0.007
Isometric strength	19.9 ± 4.3	22.6 ± 10.4	1.0±1.2	4.7±5.0	-3.7 (-6.6 - -0.8)	0.017
Kendall	31 ± 5	38 ± 10	0.0±0.0	3.8±8.2	-3.8 (-8.3 - 0.7)	0.095
Daniel	3 ± 1	3 ± 1	0.0±0.0	0.4±0.6	-0.4 (-0.7 - -0.0)	0.055
Lovett	2 ± 1	3 ± 1	0.2±0.4	0.3±0.5	-0.1 (-0.4 - 0.3)	0.676