

Tenberg et al. 2024 - Effects of Kilohertz versus low-frequency electrical stimulation of the wrist extensors in patients after stroke: a randomized crossover trial

Appendix A. CONSORT checklist of information to include when reporting randomised crossover trials

Section/topic	Item No	Description	Page No*
Title†	1a	Identification as a randomised crossover trial in the title	1
Abstract†	1b	Specify a crossover design and report all information outlined in table 2	1-2
Introduction:			
Background‡	2a	Scientific background and explanation of rationale	2-3
Objectives‡	2b	Specific objectives or hypotheses	3
Methods:			
Trial design†	3a	Rationale for a crossover design. Description of the design features including allocation ratio, especially the number and duration of periods, duration of washout period, and consideration of carry over effect	2-5, 8, Fig. 3
Change from protocol‡	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	n.a.
Participants‡	4a	Eligibility criteria for participants	4
Settings and location‡	4b	Settings and locations where the data were collected	4
Interventions†	5	The interventions with sufficient details to allow replication, including how and when they were actually administered	5-7
Outcomes‡	6a	Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed	8
Changes to outcomes‡	6b	Any changes to trial outcomes after the trial commenced, with reasons	n.a.
Sample size†	7a	How sample size was determined, accounting for within participant variability	4-5
Interim analyses and stopping guidelines‡	7b	When applicable, explanation of any interim analyses and stopping guidelines	n.a.
Randomisation:			
Sequence generation‡	8a	Method used to generate the random allocation sequence	5
Sequence generation‡	8b	Type of randomisation; details of any restriction (such as blocking and block size)	5
Allocation concealment mechanism‡	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	5
Implementation†	10	Who generated the random allocation sequence,§ who enrolled participants, and who assigned participants to the sequence of interventions	5
Blinding‡	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	5

Similarity of interventions‡	11b	If relevant, description of the similarity of interventions	5-7
Statistical methods†	12a	Statistical methods used to compare groups for primary and secondary outcomes which are appropriate for crossover design (that is, based on within participant comparison)	9
Additional analyses‡	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	9
Results			
Participant flow (a diagram is strongly recommended)†	13a	The numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome, separately for each sequence and period	Fig. 3
Losses and exclusions†	13b	No of participants excluded at each stage, with reasons, separately for each sequence and period	Fig. 3
Recruitment‡	14a	Dates defining the periods of recruitment and follow-up	4
Trial end‡	14b	Why the trial ended or was stopped	n.a.
Baseline data†	15	A table showing baseline demographic and clinical characteristics by sequence and period	Tab. 1
Numbers analysed†	16	Number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	9
Outcomes and estimation†	17a	For each primary and secondary outcome, results including estimated effect size and its precision (such as 95% confidence interval) should be based on within participant comparisons.¶ In addition, results for each intervention in each period are recommended	Tab. 3
Binary outcomes‡	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	n.a.
Ancillary analyses‡	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory	9-11, Appendix B
Harms†	19	Describe all important harms or untended effects in a way that accounts for the design (for specific guidance, see CONSORT for harms ³²)	n.a.
Discussion:			
Limitations†	20	Trial limitations, addressing sources of potential bias, imprecision, and if relevant, multiplicity of analyses. Consider potential carry over effects	17
Generalisability‡	21	Generalisability (external validity, applicability) of the trial findings	17
Interpretation‡	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	12-14
Other information:			
Registration‡	23	Registration number and name of trial registry	2
Protocol‡	24	Where the full trial protocol can be accessed, if available	n.a.
Funding‡	25	Sources of funding and other support (such as supply of drugs), role of funders	Title page

CONSORT=Consolidated Standards of Reporting Trials.

*Note: page numbers are optional depending on journal requirements.

†Modified original CONSORT item.

‡Unmodified CONSORT item.

§Random sequence here refers to a list of random orders, typically generated through a computer program. This should not be confused with the sequence of interventions in a randomised crossover trial, for example receiving intervention A before B for an individual trial participant.

¶A within participant comparison takes into account the correlation between measurements for each participant because they act as their own control, therefore measurements are not independent.

Appendix B. Linear mixed effects model results with covariates

	Efficiency (Electrically-induced Force / Stimulation Intensity) [N/mA] (n=19)	Electrically-induced Force [N] (n=19)	Discomfort [Numerical rating scale, 0-10] (n=18)	Muscle Fatigue (Decrease in Electrically-induced force) [N]
<i>Fixed Effects</i>	<i>Estimates (CI), t, p</i>	<i>Estimates (CI), t, p</i>	<i>Estimates (CI), t, p</i>	<i>Estimates (CI), t, p</i>
(Intercept)	0.16 (-0.05 to 0.37), t=1.53, p=0.126	4.70 (1.12 to 8.27), t=2.58, p= 0.010	-8.21 (-14.60 to -1.81), t=-2.52, p= 0.012	
Step	0.04 (0.03 to 0.06), t=5.24, p< 0.001	2.07 (1.45 to 2.70), t=6.51, p< 0.001	0.23 (0.13 to 0.34), t=4.30, p< 0.001	
Current Type	0.12 (0.02 to 0.22), t=2.34, p= 0.020	-1.39 (-4.16 to 1.37), t=-0.99, p=0.323	-0.29 (-0.82 to 0.24), t=-1.07, p=0.284	
MVIC	0.0 (0.00 to 0.01), t= 2.83, p= 0.005	0.06 (0.02 to 0.10), t=2.86, p= 0.004	-0.01 (-0.03 to 0.01), t= -1.01, p=0.314	
Stroke Type	-0.07 (-0.28 to 0.14), t=-0.65, p=0.513	-0.81 (-3.76 to 2.13), t=-0.54, p=0.588	-0.04 (-1.40 to 1.32), t=-0.06, p=0.954	
Pressure pain threshold			1.27 (0.46 to 2.08), t= 3.09, p= 0.002	

Sex			0.31 (-0.86 to 1.47), t=0.52, p=0.605
Lever Arm			1.0 (0.19 to 1.81), t=2.42, p= 0.016
Step:CurrentType	0.01 (0.00 to 0.02), t=2.62, p= 0.009	0.09 (-0.15 to 0.33), t=0.74, p=0.461	0.02 (-0.01 to 0.05), t=1.55, p=0.121

<i>Random Effects</i>	<i>Variance ± SD</i>	<i>Variance ± SD</i>	<i>Variance ± SD</i>	<i>Variance ± SD</i>
σ^2	0.03 ± 0.16	18.34 ± 4.28	0.25 ± 0.50	
τ_{00} Participant	0.03 ± 0.18	21.94 ± 4.68	3.22 ± 1.79	
τ_{11} Participant.Step	0.001 ± 0.03	1.79 ± 1.34	0.05 ± 0.22	
τ_{11} Participant.CurrentTypeLow-frequency	0.03 ± 0.17	23.51 ± 4.85	1.13 ± 1.06	
<i>Mixed model Information</i>	ICC, Observations	ICC, Observations	ICC, Observations	ICC, Observations
	Marginal R ² / Conditional R ²	Marginal R ² / Conditional R ²	Marginal R ² / Conditional R ²	Marginal R ² / Conditional R ²
	0.80, 444	0.87, 444	0.97, 420	Model failed to converge
	0.269 / 0.854	0.272 / 0.908	0.222 / 0.974	

N = Newton; mA = miliampere; CI = confidence interval; t = t-statistic; p = significance level; SD = standard deviation; MVIC = maximal voluntary isometric contraction; σ^2 = residual; Low-frequency = low-frequency stimulation; ICC = Intraclass Correlation Coefficient; R² = variance clarification through fixed (marginal), and fixed and random effects (conditional)