

Completed CONSORT 2010 Checklist

Note: This checklist was completed for the pilot parallel-group randomized controlled neuroimaging study. Page numbers refer to the main manuscript unless Supplementary Materials are specified. Items not applicable to this design are marked accordingly.

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract	1a	Identification as a randomised trial in the title	p. 1 (identified as a pilot randomized controlled neuroimaging study)
Title and abstract	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	pp. 2–3
Introduction: Background and objectives	2a	Scientific background and explanation of rationale	pp. 3–5
Introduction: Background and objectives	2b	Specific objectives or hypotheses	p. 5
Methods: Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	pp. 5–7 (parallel two-arm design; 1:1 allocation)
Methods: Trial design	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	Not applicable after trial commencement. Final operational eligibility criteria were revised before recruitment, approved by the ethics committee, and applied prospectively to all participants; Supplementary Text S6, p. 4.
Methods: Participants	4a	Eligibility criteria for participants	pp. 5–7; Supplementary Text S6, p. 4
Methods: Participants	4b	Settings and locations where the data were collected	pp. 5–6 (recruitment at Shanghai Hebin Rehabilitation Hospital); pp. 9–10 (MRI at Huashan Hospital)
Methods: Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	pp. 7–8
Methods: Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	pp. 2, 5, and 9; Table 2, p. 33
Methods: Outcomes	6b	Any changes to trial outcomes after the trial commenced, with reasons	Not applicable; no changes to trial outcomes after commencement were reported
Methods: Sample size	7a	How sample size was determined	p. 7 (pragmatic sample of 24 informed by the previous REX pilot trial)
Methods: Sample size	7b	When applicable, explanation of any interim analyses and stopping guidelines	Not applicable; no interim analyses or stopping guidelines were used
Methods: Randomisation - Sequence generation	8a	Method used to generate the random allocation sequence	p. 7 (computer-generated random-number sequence)
Methods: Randomisation - Sequence generation	8b	Type of randomisation; details of any restriction (such as blocking and block size)	p. 7 (1:1 allocation; no restricted randomisation was reported)
Methods: 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	p. 7 (sequentially numbered, opaque, sealed envelopes opened after baseline assessment and enrolment)
Methods: Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	p. 7 (independent researchers generated the sequence and prepared/held the envelopes; personnel responsible for enrolment and assignment were not explicitly identified)
Methods: Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	p. 7 (outcome assessors blinded; participants and treating therapists could not be blinded)
Methods: Blinding	11b	If relevant, description of the similarity of interventions	pp. 7–8 (both groups received conventional rehabilitation plus 60-minute additional upright training for 5 days/week over 4 weeks; device-specific exposure differed)
Methods: Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	p. 9 (clinical outcomes); pp. 11–12 (imaging and brain-behaviour analyses)

Section/Topic	Item No	Checklist item	Reported on page No
Methods: Statistical methods	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	p. 9; pp. 11–12; Supplementary Texts S1–S5, pp. 2–3; Supplementary Tables S1–S10, pp. 5–10
Results: Participant flow	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	p. 13; Figure 1, p. 27
Results: Participant flow	13b	For each group, losses and exclusions after randomisation, together with reasons	pp. 11 and 13; Figure 1, p. 27 (clinical follow-up complete; four imaging exclusions with reasons)
Results: Recruitment	14a	Dates defining the periods of recruitment and follow-up	pp. 5 and 8 (recruitment from 26 December 2023 to 25 December 2024; 4-week follow-up)
Results: Recruitment	14b	Why the trial ended or was stopped	Not applicable; the trial completed the planned recruitment and 4-week follow-up and was not stopped early
Results: Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1, p. 32
Results: Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	pp. 13–14; Figure 1, p. 27; Tables 1–2, pp. 32–33
Results: 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)	pp. 13–14; Table 2, p. 33; Supplementary Table S1, p. 5
Results: Outcomes and estimation	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	Not applicable; no binary outcomes were analysed
Results: Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	pp. 14–16; Supplementary Texts S1–S5, pp. 2–3; Supplementary Tables S1–S10, pp. 5–10
Results: Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	p. 8 and p. 13 (no adverse events occurred during the intervention period)
Discussion: Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	pp. 18–19
Discussion: Generalisability	21	Generalisability (external validity, applicability) of the trial findings	p. 19 (pilot sample, imaging subset, and need for larger preregistered trials)
Discussion: Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	pp. 16–20
Other information: Registration	23	Registration number and name of trial registry	p. 3 and pp. 5–6
Other information: Protocol	24	Where the full trial protocol can be accessed, if available	p. 3 and pp. 5–6 (trial registry record; a full protocol is not stated as separately available)
Other information: Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	p. 21