CONSORT 2025 checklist of information to include when reporting a randomised trial*

Section / Topic	No	CONSORT 2025 checklist item description	Reported on page no.
Title and abstract			
Title and structured abstract	1a	Identification as a randomised trial	Page 1 (Manuscript title)
	1b	Structured summary of the trial design, methods, results, and conclusions	Page 1, Abstract; Submitted to Chinese Clinical Trial Registry (ChiCTR) on 31 July 2026, registration number pending official approval
Open science			
Trial registration	2	Name of trial registry, identifying number (with URL) and date of registration	Page 1, Abstract; Registered with ChiCTR, registration number

			pending review
Protocol and statistical analysis plan	3	Where the trial protocol and statistical analysis plan can be accessed	N/A, No separate uploaded trial protocol; full protocol described in Methods section
Data sharing	4	Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed	Page 25, Declarations: Availability of data and materials
Funding and conflicts of interest	5a	Sources of funding and other support (e.g., supply of drugs), and role of funders in the design, conduct, analysis and reporting of the trial	Page 25, Declarations: Funding
	5b	Financial and other conflicts of interest of the manuscript authors	Page 25, Declarations: Competing interests
Introduction			
Background and rationale	6	Scientific background and rationale	Pages 2–4, Background section
Objectives	7	Specific objectives related to benefits and harms	Page 4, last paragraph of Introduction
Methods			

Patient and public involvement	8	Details of patient or public involvement in the design, conduct and reporting of the trial	N/A, No patient/public engagement conducted in this trial
Trial design	9	Description of trial design including type of trial (e.g., parallel group, crossover), allocation ratio, and framework (e.g., superiority, equivalence, non-inferiority, exploratory)	Page 4, 2.1 Study design
Changes to trial protocol	10	Important changes to the trial after it commenced including any outcomes or analyses that were not prespecified, with reason	N/A, No protocol or outcome changes during the trial
Trial setting	11	Settings (e.g., community, hospital) and locations (e.g., countries, sites) where the trial was conducted	Page 4, Single-center rehabilitation department, Wuhan Sixth Hospital
Eligibility criteria	12a	Eligibility criteria for participants	Pages 4–5, 2.2.1 & 2.2.2 Inclusion/Exclusion criteria
	12b	If applicable, eligibility criteria for sites and for individuals delivering the interventions (e.g., surgeons, physiotherapists)	N/A, No additional site/staff eligibility rules set
Intervention and comparator	13	Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (e.g., intervention manual) can be accessed	Pages 5–7, 2.3 four-

			group intervention protocols with full device parameters
Outcomes	14	Pre-specified primary and secondary outcomes, including the specific measurement variable (e.g., systolic blood pressure), analysis metric (e.g., change from baseline, final value, time to event), method of aggregation (e.g., median, proportion), and time point for each outcome	Pages 7–9, 2.5–2.6 fNIRS & behavioral outcome assessments
Harms	15	How harms were defined and assessed (e.g., systematically, non-systematically)	N/A, No systematic adverse event assessment protocol was set, and no adverse reactions were reported by any participant during the whole intervention
Sample size	16a	How sample size was determined, including all assumptions supporting the sample size calculation	N/A, Single-center exploratory trial without formal

			sample size calculation
	16b	Explanation of any interim analyses and stopping guidelines	N/A, No interim analysis or early stopping rule applied
Randomisation:			
Sequence generation	17a	Who generated the random allocation sequence and the method used	Page 5, Independent statistician used computer random sequence generation
	17b	Type of randomisation and details of any restriction (e.g., stratification, blocking and block size)	N/A, Simple randomization only, no stratification /blocking
Allocation concealment mechanism	18	Mechanism used to implement the random allocation sequence (e.g., central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned	Page 5, Sequentially numbered opaque sealed envelopes
Implementation	19	Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence	Page 5, Recruitment staff blinded to random allocation

Blinding	20a	Who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors, data analysts)	Page 5; Outcome evaluators and statistical analysts were fully blinded; participants and rehabilitation therapists could not be blinded due to different intervention modalities
	20b	If blinded, how blinding was achieved and description of the similarity of interventions	N/A, Physical intervention types cannot be masked to participants/ therapists
Statistical methods	21a	Statistical methods used to compare groups for primary and secondary outcomes, including harms	Pages 9–10, 2.8 Statistical analysis section
	21b	Definition of who is included in each analysis (e.g., all randomised participants), and in which group	Page 10, All randomized participants

			per-protocol analysis
	21c	How missing data were handled in the analysis	N/A, No missing participant data in this trial
	21d	Methods for any additional analyses (e.g., subgroup and sensitivity analyses), distinguishing prespecified from post-hoc	Pages 16–18, Pre-specified linear regression & Pearson correlation
Results			
Participant flow, including flow diagram	22a	For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome	Page 10, Table 1 baseline demographics; all 36 participants fully completed trial
	22b	For each group, losses and exclusions after randomisation, together with reasons	N/A, Zero participant dropout or exclusion
Recruitment	23a	Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms	Page 4, Recruitment: Jan–Dec 2025; 2-week

			intervention follow-up
	23b	If relevant, why the trial ended or was stopped	N/A, Trial completed as originally planned
Intervention and comparator delivery	24a	Intervention and comparator as they were actually administered (e.g., where appropriate, who delivered the intervention/comparator, how participants adhered, whether they were delivered as intended [fidelity])	Pages 5–7, All participants finished 10 full intervention sessions
	24b	Concomitant care received during the trial for each group	Page 5, All groups received identical standard rehabilitation
Baseline data	25	A table showing baseline demographic and clinical characteristics for each group	Page 10, Table 1
Numbers analysed, outcomes and estimation	26	For each primary and secondary outcome, by group: ● the number of participants included in the analysis ● the number of participants with available data at the outcome time point ● result for each group, and the estimated effect size and its precision (such as 95% confidence interval) ● for binary outcomes, presentation of both absolute and relative effect size	Pages 11–16, Table 2, Table 3, Figure 3 & Figure 4
Harms	27	All harms or unintended events in each group	N/A, No adverse events

			recorded in any group
Ancillary analyses	28	Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post-hoc	Pages 16–18, Table4 regression, Table5 correlation (pre-specified)
Discussion			
Interpretation	29	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Pages 18–22, full Discussion section
Limitations	30	Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses	Page 23, 4.6 Limitations subsection

*We strongly recommend reading this statement in conjunction with the CONSORT 2025 Explanation and Elaboration and/or the CONSORT 2025 Expanded Checklist for important clarifications on all the items. We also recommend reading relevant CONSORT extensions. See www.consort-spirit.org.

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