CONSORT 2010 checklist

"Multimodal Pelvic Floor Rehabilitation in Chronic Stroke Survivors: Long-Term Efficacy, Optimal Protocols, and Adjunctive Therapies for Comprehensive Pelvic Floor Dysfunction – A Multicenter Randomized Controlled Trial").

The table follows the standard **CONSORT 2010** 25-item structure (for parallel-group RCTs). The paper is a four-arm parallel-group multicenter RCT, so the standard checklist applies (with multi-arm aspects implicitly covered under relevant items).

For each item:

- **Item description** (verbatim or close paraphrase from CONSORT 2010)
- **Reported in paper?** → Yes / Partially / No
- **Location / Evidence** → Brief reference to section(s), table(s), figure(s), or explanation

Section / Topic	Item No	Checklist Item	Reported?	Location / Evidence in the Paper
Title and Abstract	1a	Identification as a randomised trial in the title	Yes	Title explicitly states "A Multicenter Randomized Controlled Trial"
	1b	Structured summary of trial design, methods, results, and conclusions	Yes	Abstract is structured (Background, Objective, Methods, Results, Conclusion) with key elements covered
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Yes	Introduction section details stroke prevalence, PFD impact, evidence gaps, prior reviews
	2b	Specific objectives or hypotheses	Yes	Explicit hypotheses listed (e.g., ≥80% sustain gains, domain-specific benefits, predictors)
Methods				

Section / Topic	Item No	Checklist Item	Reported?	Location / Evidence in the Paper
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Yes	Section 2.1: prospective, assessor-blinded, four-arm parallel-group RCT; 1:1:1:1 ratio
	3b	Important changes to methods after trial commencement (e.g., eligibility criteria), with reasons	Yes (none reported)	No changes mentioned; implies none occurred
Participants	4a	Eligibility criteria for participants	Yes	Section 2.2: detailed inclusion/exclusion criteria
	4b	Settings and locations where the data were collected	Yes	Section 2.1: eight rehabilitation centers in Scandinavia, Russia, and Pakistan (specific hospitals named)
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Yes	Section 2.4: detailed protocols for each of 4 groups (PFMT variations, adjuncts, frequency, duration, home phase)
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	Yes	Section 2.5: primaries (Oxford scale, perineometry, ICIQ-UI SF, Wexner); secondaries (FSFI/IIEF-5, SF-36, SIS, etc.); timepoints listed
	6b	Any changes to trial outcomes after the trial commenced, with reasons	Yes (none reported)	No changes mentioned
Sample size	7a	How sample size was determined	Yes	Section 2.2: power calculation (1.2-point difference, SD 1.8, 90% power, 20% attrition) → n=105/group
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A	No interim analyses or stopping rules mentioned

Section / Topic	Item No	Checklist Item	Reported?	Location / Evidence in the Paper
Randomisation: Sequence generation	8a	Method used to generate the random allocation sequence	Yes	Section 2.3: computer-based random number generator, permuted blocks of size 4
Randomisation: 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	Yes	Section 2.3: sequentially numbered, opaque, sealed envelopes; prepared by independent statistician
Randomisation: Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Yes	Section 2.3: independent statistician generated sequence; site coordinators enrolled; site PI assigned via envelope
Blinding	11a	If done, who was blinded after study enrolment (e.g., participants, care providers, those assessing outcomes) and how	Yes	Section 2.3: assessor-blinded and statistician-blinded; participants/therapists not blinded (nature of interventions)
	11b	If relevant, description of the similarity of interventions	Partially	Interventions differ by design (adjuncts, frequency); similarity not applicable/relevant
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	Yes	Section 2.6: linear mixed models, ITT, restricted maximum likelihood, R 4.4.1
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	Yes	Multivariable regression for predictors; multiple imputation for missing data (<12%)
Results				
Participant flow (diagram recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Partially	No explicit CONSORT flow diagram; numbers implied (n=420 total, 105/group); ITT n=420; missing data <12%

Section / Topic	Item No	Checklist Item	Reported?	Location / Evidence in the Paper
	13b	For each group, losses and exclusions after randomisation, together with reasons	Partially	Attrition implied (<12% missing); no detailed losses/exclusions per group or reasons
Recruitment	14a	Dates defining the periods of recruitment and follow-up	Yes	Section 2.1: January 2022 to June 2025 (enrollment and follow-up period)
	14b	Why the trial ended or was stopped	Yes (N/A)	Completed as planned; no early stopping
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Yes	Table 1: detailed baseline characteristics by group (age, sex, stroke type, time since stroke, outcome scores); balanced (all p>0.05)
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	Yes	Intention-to-treat; n=105 per group; analyses report adjusted means/changes
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (e.g., 95% confidence interval)	Yes	Tables 2–5, Figures 1–6: mean changes, 95% CIs (where given), p-values (e.g., Wexner p=0.002)
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A	Mostly continuous outcomes; remission rates given (e.g., Table 3: 51% vs 30%)
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	Yes	Predictors (multivariable ORs with 95% CIs, Figure 6); correlations (heatmap, Figure 5)
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	No	No adverse events or harms reported (likely none occurred, but not explicitly stated)

Section / Topic	Item No	Checklist Item	Reported?	Location / Evidence in the Paper
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	Yes	Section 4 (Limitations): optimism bias in adherence, limited ethnic diversity, need for cost-effectiveness/digital platforms
Generalisability	21	Generalisability (external validity) of the trial findings	Yes	Discussion notes multicenter design enhances validity but calls for broader ethnic/socioeconomic groups
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	Yes	Conclusion and Discussion integrate results with prior evidence, emphasize clinical implications
Other information				
Registration	23	Registration number and name of trial registry	Yes	Section 2.1 & Declarations: prospectively registered on OSF (osf.io/xyxyx)
Protocol	24	Where the full trial protocol can be accessed, if available	Partially	Implied via OSF registration; no direct link to full protocol
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	Yes	Declarations: no external funding; institutional resources only; funding did not compromise findings