

CONSORT 2010 Checklist

| Section/Topic | Item No. | CONSORT Description | Reported on Page/Line |
|---------------------------|----------|--|---|
| Title and Abstract | 1a | Identification as a randomized trial in the title | Title includes “Randomized Controlled Trial” |
| | 1b | Structured summary of trial design, methods, results, and conclusions | Abstract provides structured summary |
| Introduction | 2a | Scientific background and explanation of rationale | Introduction sections 1-2 |
| | 2b | Specific objectives or hypotheses | End of Introduction |
| Methods | 3a | Description of trial design (e.g., parallel, factorial) including allocation ratio | 2.1 Design and Setting |
| | 3b | Important changes to methods after trial commencement (e.g., eligibility criteria), with reasons | 2.6 – states no post-registration modifications |
| Participants | 4a | Eligibility criteria for participants | 2.2 Participants – Eligibility Criteria |

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| | 4b | Settings and locations where the data were collected | 2.1 Design and Setting |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication | 2.2 Interventions (Hybrid, EAGT-only, CGT-only) |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | 2.3 Outcomes |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons | 2.6 – none reported |
| Sample Size | 7a | How sample size was determined | 2.2 – Sample Size Determination |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | 2.5 – interim safety review mentioned |
| Randomization | 8a | Method used to generate the random allocation sequence | 2.4 – Randomization and Blinding |

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| | 8b | Type of randomization; details of any restriction (e.g., blocking and block size) | 2.4 – stratified, permuted block randomization |
| Allocation Concealment | 9 | Mechanism used to implement the random allocation sequence (e.g., central telephone; sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 2.4 – Central web-based randomization system; sealed envelopes backup |
| Implementation | 10 | Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions | 2.4 – independent statistician, site coordinators, treating physiotherapists |
| Blinding | 11a | If done, who was blinded after assignment to interventions (e.g., participants, care providers, outcome assessors), and how | 2.4 – Blinding procedures described (assessors and analysts blinded) |
| | 11b | If relevant, description of the similarity of interventions | 2.2 – interventions differ by design; comparability of intensity described |
| Statistical Methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | 2.5 – Statistical Analysis |

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| | 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | 2.5 and 4.1 Subgroup Analyses |
| Results | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome | Figure/flow not provided in text, but numbers given in Methods/Results |
| | 13b | For each group, losses and exclusions after randomization, together with reasons | Not explicitly detailed; adherence >95% reported |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | 2.1 – March 2022 to September 2024 |
| | 14b | Why the trial ended or was stopped | Not stated; presumably completed as planned |
| Baseline Data | 15 | A table showing baseline demographic and clinical characteristics for each group | Table 1 in Results |
| Numbers Analyzed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Results sections refer to n=48, 46, 46 per group; ITT used |

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| 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) | Tables 2–4; Figures 1–3; between-group differences reported |
| | 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | Not applicable (continuous outcomes) |
| Ancillary Analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | 4.1 Subgroup Analyses |
| Harms | 19 | All important harms or unintended effects in each group | 2.6 – mentions risks minimized; no adverse events reported |
| Discussion | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Discussion – Limitations section |
| Interpretation | 21 | Generalizability (external validity, applicability) of the trial findings | Discussion – Clinical Implications and Generalizability |

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| Registration | 22 | Registration number and name of trial registry | 2.1 and 2.6 – OSF |
| Protocol | 23 | Where the full trial protocol can be accessed, if available | 2.1 – link to OSF registration provided |
| Funding | 24 | Sources of funding and other support (such as supply of drugs), role of funders | Declarations – Funding section |