

# The CONSORT reporting checklist

For checking that reports of randomised trials can be understood and used by everyone

|                                           | Item Description                                                                                                                                                                   | Location (or reason for not reporting)       |
|-------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|
| <b>Title and Abstract</b>                 |                                                                                                                                                                                    |                                              |
| 1a. Title                                 | Identification as a randomised trial.                                                                                                                                              | Page 1                                       |
| 1b. Structured Abstract                   | Structured summary of the trial design, methods, results, and conclusions.                                                                                                         | Page 2                                       |
| <b>Open Science</b>                       |                                                                                                                                                                                    |                                              |
| 2. Trial Registration                     | Name of trial registry, identifying number and date of registration.                                                                                                               | Page 2, 6                                    |
| 3. Protocol and statistical analysis plan | Where the trial protocol and statistical analysis plan can be accessed.                                                                                                            | Not Applicable.                              |
| 4. Data sharing                           | Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed.                                 | Page 22 (Availability of data and materials) |
| 5. Funding and Conflicts of Interest      |                                                                                                                                                                                    |                                              |
| 5a. Funding                               | Sources of funding and other support (eg, supply of drugs), and role of funders in the design, conduct, analysis, and reporting of the trial.                                      | Page 22 (Funding)                            |
| 5b. Conflicts of interest                 | Financial and other conflicts of interest of the manuscript authors.                                                                                                               | Page 22 (Competing interests)                |
| <b>Introduction</b>                       |                                                                                                                                                                                    |                                              |
| 6. Background and rationale               | Scientific background and rationale.                                                                                                                                               | Pages 3-5                                    |
| 7. Objectives                             | Specific objectives related to benefits and harms.                                                                                                                                 | Pages 4-5                                    |
| <b>Methods</b>                            |                                                                                                                                                                                    |                                              |
| 8. Patient and public involvement         | Details of patient or public involvement in the design, conduct and reporting of the trial.                                                                                        | Not applicable                               |
| 9. Trial Design                           | Description of trial design including type of trial (eg, parallel group, crossover), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory). | Page 5                                       |
| 10. Changes to trial                      | Important changes to the trial after it commenced                                                                                                                                  | Not applicable                               |

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| protocol                                    | including any outcomes or analyses that were not pre-specified, with reason.                                                                                                                                                                                                     |                                 |
| 11. Trial Setting                           | Settings (eg, community, hospital) and locations (eg, countries, sites) where the trial was conducted.                                                                                                                                                                           | Page 6                          |
| 12. Eligibility Criteria                    |                                                                                                                                                                                                                                                                                  |                                 |
| 12a. Participants                           | Eligibility criteria for participants.                                                                                                                                                                                                                                           | Page 6                          |
| 12b. Other                                  | If applicable, eligibility criteria for sites and for individuals delivering the interventions (eg, surgeons, physiotherapists).                                                                                                                                                 | Not applicable                  |
| 13. Intervention and comparator             | Intervention and comparator with sufficient details to allow replication. If relevant, where additional materials describing the intervention and comparator (eg, intervention manual) can be accessed.                                                                          | Pages 7-9 (Procedure)           |
| 14. Outcomes                                | Prespecified primary and secondary outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. | Pages 9-11                      |
| 15. Harms                                   | How harms were defined and assessed (eg, systematically, non-systematically).                                                                                                                                                                                                    | Not applicable                  |
| 16. Sample Size                             |                                                                                                                                                                                                                                                                                  |                                 |
| 16a. How sample size was determined         | How sample size was determined, including all assumptions supporting the sample size calculation.                                                                                                                                                                                | Page 6                          |
| 16b. Interim analyses and stopping criteria | Explanation of any interim analyses and stopping guidelines.                                                                                                                                                                                                                     | Not applicable                  |
| 17. Randomisation                           |                                                                                                                                                                                                                                                                                  |                                 |
| 17a. Sequence Generation                    | Who generated the random allocation sequence and the method used.                                                                                                                                                                                                                | Page 8                          |
| 17b. Type of Randomisation                  | Type of randomisation and details of any restriction (eg, stratification, blocking, and block size).                                                                                                                                                                             | Page 8                          |
| 18. Allocation concealment mechanism        | Mechanism used to implement the random allocation sequence (eg, central computer/telephone; sequentially numbered, opaque, sealed containers), describing any steps to conceal the sequence until interventions were assigned.                                                   | Not applicable                  |
| 19. Implementation                          | Whether the personnel who enrolled and those who assigned participants to the interventions had access to the random allocation sequence.                                                                                                                                        | Page 8                          |
| 20. Blinding                                |                                                                                                                                                                                                                                                                                  |                                 |
| 20a. Who was                                | Who was blinded after assignment to interventions                                                                                                                                                                                                                                | Not applicable (Blinding is not |

|                                                     |                                                                                                                                                                                                                      |                                                                                   |
|-----------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|
| blinded                                             | (eg, participants, care providers, outcome assessors, data analysts).                                                                                                                                                | possible for exercise interventions)                                              |
| 20b. How blinding was achieved                      | If blinded, how blinding was achieved and description of the similarity of interventions.                                                                                                                            | Not applicable                                                                    |
| 21. Statistical methods                             |                                                                                                                                                                                                                      |                                                                                   |
| 21a. Comparing groups                               | Statistical methods used to compare groups for primary and secondary outcomes, including harms.                                                                                                                      | Pages 11, 12                                                                      |
| 21b. Definition of who is included in each analysis | Definition of who is included in each analysis (e.g., all randomised participants), and in which group.                                                                                                              | Page 11                                                                           |
| 21c. Missing Data                                   | How missing data were handled in the analysis.                                                                                                                                                                       | Not applicable (No missing data)                                                  |
| 21d. Additional Analyses                            | Methods for any additional analyses (eg, subgroup and sensitivity analyses), distinguishing pre-specified from post hoc.                                                                                             | Not applicable                                                                    |
| 22. Participant flow, including flow diagram        |                                                                                                                                                                                                                      |                                                                                   |
| 22a. Participant Numbers                            | For each group, the numbers of participants who were randomly assigned, received intended intervention, and were analysed for the primary outcome.                                                                   | Page 7 (Figure 1), Page 11                                                        |
| 22b. Losses and exclusions                          | For each group, losses and exclusions after randomisation, together with reasons.                                                                                                                                    | Page 7 (Figure 1 - n=0)                                                           |
| 23. Recruitment                                     |                                                                                                                                                                                                                      |                                                                                   |
| 23a. Dates                                          | Dates defining the periods of recruitment and follow-up for outcomes of benefits and harms.                                                                                                                          | Page 6                                                                            |
| 23b. Reasons for stopping recruitment               | If relevant, why the trial ended or was stopped.                                                                                                                                                                     | Not applicable                                                                    |
| 24. Intervention and comparator delivery            |                                                                                                                                                                                                                      |                                                                                   |
| 24a. As Administered                                | Intervention and comparator as they were actually administered (eg, where appropriate, who delivered the intervention/comparator, whether participants adhered, whether they were delivered as intended (fidelity)). | Pages 7-9                                                                         |
| 24b. Concomitant Care                               | Concomitant care received during the trial for each group.                                                                                                                                                           | Page 6 (Refraining from resistance training)                                      |
| 25. Baseline Data                                   | A table showing baseline demographic and clinical characteristics for each group.                                                                                                                                    | Page 6 (Reported in text instead of a table due to single-group crossover design) |

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| 26. Numbers analysed, outcomes, and estimation | <p>For each primary and secondary outcome, by group:</p> <ul style="list-style-type: none"> <li>the number of participants included in the analysis.</li> <li>the number of participants with available data at the outcome time point.</li> <li>result for each group, and the estimated effect size and its precision (such as 95% confidence interval).</li> <li>for binary outcomes, presentation of both absolute and relative effect size.</li> </ul> | Pages 12-16 (Tables 1, 2, 3, 4) |
| 27. Harms                                      | All harms or unintended events in each group.                                                                                                                                                                                                                                                                                                                                                                                                               | Not applicable                  |
| 28. Ancillary Analyses                         | Any other analyses performed, including subgroup and sensitivity analyses, distinguishing pre-specified from post hoc.                                                                                                                                                                                                                                                                                                                                      | Not applicable                  |
| <b>Discussion</b>                              |                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                 |
| 29. Interpretation                             | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence.                                                                                                                                                                                                                                                                                                                                              | Pages 16-19                     |
| 30. Limitations                                | Trial limitations, addressing sources of potential bias, imprecision, generalisability, and, if relevant, multiplicity of analyses.                                                                                                                                                                                                                                                                                                                         | Page 20                         |