CONSORT 2010 checklist of information to include when reporting a randomised trial\*

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| Section/Topic | Item No | Checklist item | Reported on page No |
| Title and abstract | | | |
|  | 1a | Identification as a randomised trial in the title | Manuscript p. 1 |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts) | Manuscript p. 2-3 |
| Introduction | | | |
| Background and objectives | 2a | Scientific background and explanation of rationale | Introduction paragraphs 1-3 |
| 2b | Specific objectives or hypotheses | Introduction paragraph 3 |
| Methods | | | |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Methods paragraphs1-3 |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | None. |
| Participants | 4a | Eligibility criteria for participants | Methods paragraph 1 |
| 4b | Settings and locations where the data were collected | Methods paragraph 4 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Methods paragraph 6 & Table |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Methods paragraph 4 , Appendices S2-S4 |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons | None. |
| Sample size | 7a | How sample size was determined | Methods paragraph 8 |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | Not applicable |
| Randomisation: |  |  |  |
| Sequence generation | 8a | Method used to generate the random allocation sequence | Methods paragraph 3 |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Methods paragraph 3 |
| 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 | Methods paragraph 3 |
| Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Methods paragraph 3 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | Methods paragraph 4 |
| 11b | If relevant, description of the similarity of interventions | Not applicable |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | Methods Paragraph 7-10 *Appendix S11* |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | Methods Paragraph 7-10 *Appendix S11* |
| Results | | | |
| Participant flow (a diagram is strongly recommended) | 13a | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome | Results paragraphs 1 and 2 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons | Fig 1 |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up | Manuscript p.2 & 5 |
| 14b | Why the trial ended or was stopped | Not applicable trial completed as planned |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Table 2 |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | Results paragraph 3 & Table 3 |
| 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) | Table 3 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | Not applicable no binary outcomes presented |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory | Table 4 and Supplementary Web appendices 9-11 |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms) | Results paragraph 6 |
| Discussion | | | |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | Manuscript p.12-13 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Manuscript p.12 & 13 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | Manuscript p11-13 |
| Other information | | |  |
| Registration | 23 | Registration number and name of trial registry | Manuscript p3 |
| Protocol | 24 | Where the full trial protocol can be accessed, if available | \* see Carnes D. ref below |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders | PLOS Medicine electronic form |

\* Carnes D, Underwood M, Homer K, Bremner S, Eldridge S, Pincus T, Rahman A, Taylor SJC. Effectiveness and cost effectiveness of a novel, group self-management course for adults with chronic musculoskeletal pain: study protocol for a multi-centre, randomised controlled trial (COPERS). *BMJ Open* 2013; 3:e002492

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).