**S1 Checklist. Consolidated Standards Of Reporting Trials (CONSORT) Checklist.**

**Darlow B, Stanley J, Dean S, Abbott JH, Garrett S, Wilson W, Mathieson F, Dowell A (2019) *The Fear Reduction Exercised Early (FREE) approach to management of low back pain in general practice: a pragmatic cluster-randomised controlled trial* published in PLOS Medicine**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Section/Topic | Item No | Standard Checklist item | Extension for cluster designs | Section and paragraph No\* |
| Title and abstract |  |
|  | 1a | Identification as a randomised trial in the title | Identification as a cluster randomised trial in the title | Title |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[[1]](#endnote-1),[[2]](#endnote-2) | See table 2 | Abstract |
| Introduction |  |
| Background and objectives | 2a | Scientific background and explanation of rationale | Rationale for using a cluster design | Introduction, para 3 |
| 2b | Specific objectives or hypotheses | Whether objectives pertain to the cluster level, the individual participant level or both | Introduction, para 3 |
| Methods |  |
| Trial design | 3a | Description of trial design (such as parallel, factorial) including allocation ratio | Definition of cluster and description of how the design features apply to the clusters | Methods, Study Design, para 1 |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |  | Methods, Participants, para 3 |
| Participants | 4a | Eligibility criteria for participants | Eligibility criteria for clusters  | Methods, Participants, para 3 |
| 4b | Settings and locations where the data were collected |  | Methods, Participants, para 2 - 3 |
| Interventions | 5 | The interventions for each group with sufficient details to allow replication, including how and when they were actually administered | Whether interventions pertain to the cluster level, the individual participant level or both | Methods, Procedures, para 1, Figure 1, S2 and S3 |
| Outcomes | 6a | Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed | Whether outcome measures pertain to the cluster level, the individual participant level or both | Methods, Outcomes, para 1 and 3 |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons |  | NA |
| Sample size | 7a | How sample size was determined | Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty | Methods, Statistical analysis, para 1 |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines |  | NA |
| Randomisation: |  |
|  Sequence generation | 8a | Method used to generate the random allocation sequence |  | Methods, Randomisation and masking, para 1 |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Details of stratification or matching if used | Methods, Randomisation and masking, para 1 |
|  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 | Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both | Methods, Randomisation and masking, para 2 |
|  Implementation | 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Replace by 10a, 10b and 10c |  |
|  | 10a |  | Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions | Methods, Randomisation and masking, para 1 |
|  | 10b |  | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling) | Methods, Randomisation and masking, para 1 |
|  | 10c |  | From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation | Methods, Participants, para 4Methods, Randomisation and masking, para 2 |
| Blinding | 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how |  | Methods, Randomisation and masking, para 2 |
| 11b | If relevant, description of the similarity of interventions |  | Methods, Randomisation and masking, para 2 |
| Statistical methods | 12a | Statistical methods used to compare groups for primary and secondary outcomes | How clustering was taken into account | 11-13 |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses |  | Methods, Statistical analysis, para 2 to 8 |
| 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 | For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome | Figure 2 |
| 13b | For each group, losses and exclusions after randomisation, together with reasons | For each group, losses and exclusions for both clusters and individual cluster members | Figure 2, and Table S2, supplementary appendix |
| Recruitment | 14a | Dates defining the periods of recruitment and follow-up |  | Results, para 2 and Table S1, supplementary appendix |
| 14b | Why the trial ended or was stopped |  | NA |
| Baseline data | 15 | A table showing baseline demographic and clinical characteristics for each group | Baseline characteristics for the individual and cluster levels as applicable for each group | Tables 1 and 2,  |
| Numbers analysed | 16 | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups | For each group, number of clusters included in each analysis | Tables 3 and 4,  |
| 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) | Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome | Results, para 3 to 9 |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended |  | Supplementary appendix |
| Ancillary analyses | 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory |  | Supplementary appendix |
| Harms | 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[[3]](#endnote-3)) |  | Results, para 4 and supplementary appendix |
| Discussion |  |
| Limitations | 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses |  | Discussion, para 5, 7 |
| Generalisability | 21 | Generalisability (external validity, applicability) of the trial findings | Generalisability to clusters and/or individual participants (as relevant) | Discussion, para 8 |
| Interpretation | 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence |  | Discussion, para 9, 10 |
| Other information |  |  |
| Registration | 23 | Registration number and name of trial registry |  | Methods, para 1 |
| Protocol | 24 | Where the full trial protocol can be accessed, if available |  | Reference list |
| Funding | 25 | Sources of funding and other support (such as supply of drugs), role of funders |  | Methods, Role of the funding source |

*\* Note: page numbers optional depending on journal requirements*

**Part 2. Extension of CONSORT for abstractsto reports of cluster randomised trials**

|  |  |  |
| --- | --- | --- |
| Item | Standard Checklist item | Extension for cluster trials |
| Title | Identification of study as randomised | Identification of study as cluster randomised |
| Trial design | Description of the trial design (e.g. parallel, cluster, non-inferiority) | Yes |
| Methods |  |  |
| Participants | Eligibility criteria for participants and the settings where the data were collected | Eligibility criteria for clusters - Yes |
| Interventions | Interventions intended for each group | Yes |
| Objective | Specific objective or hypothesis | Whether objective or hypothesis pertains to the cluster level, the individual participant level or both - Yes |
| Outcome | Clearly defined primary outcome for this report | Whether the primary outcome pertains to the cluster level, the individual participant level or both - Yes |
| Randomization | How participants were allocated to interventions | How clusters were allocated to interventions -Yes |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | Yes |
| Results |  |  |
| Numbers randomized | Number of participants randomized to each group | Number of clusters randomized to each group Yes |
| Recruitment | Trial status[[4]](#footnote-1) |  |
| Numbers analysed | Number of participants analysed in each group | Number of clusters analysed in each group Yes |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | Results at the cluster or individual participant level as applicable for each primary outcome Yes |
| Harms | Important adverse events or side effects | Yes |
| Conclusions | General interpretation of the results |  Yes |
| Trial registration | Registration number and name of trial register | Yes |
| Funding | Source of funding | Yes |
|  |  |  |

**REFERENCES**

1. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283 [↑](#endnote-ref-1)
2. Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20 [↑](#endnote-ref-2)
3. Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788. [↑](#endnote-ref-3)
4. [↑](#footnote-ref-1)