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

| Section/topic and item No | Standard checklist item | Extension for cluster designs | Page No* |
|---|---|---|---|
| **Title and abstract** | | | |
| 1a | Identification as a randomised trial in the title | Identification as a cluster randomised trial in the title | 1 |
| 1b | Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[11 12] | See table 2 | 4 |
| **Introduction** | | | |
| Background and objectives: | | | |
| 2a | Scientific background and explanation of rationale | Rationale for using a cluster design | 5 |
| 2b | Specific objectives or hypotheses | Whether objectives pertain to the cluster level, the individual participant level, or both | 5 |
| **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 | 5-6 |
| 3b | Important changes to methods after trial commencement (such as eligibility criteria), with reasons | | N/A |
| Participants: | | | |
| 4a | Eligibility criteria for participants | Eligibility criteria for clusters | 6, 10-11 |
| 4b | Settings and locations where the data were collected | | 6-7 |
| 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 | 6-13 |
| Outcomes: | | | |
| 6a | Completely defined prespecified 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 | 9-13 |
| 6b | Any changes to trial outcomes after the trial commenced, with reasons | | N/A |
| 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 | 7 |
| 7b | When applicable, explanation of any interim analyses and stopping guidelines | | N/A |
| **Randomisation** | | | |
| Sequence generation: | | | |
| 8a | Method used to generate the random allocation sequence | | 7 |
| 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Details of stratification or matching if used | 7 |
| 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 | N/A |
| Implementation: | | | |
| 10 | Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions | Replaced by 10a, 10b, and 10c | |
| 10a | | Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions | N/A |

**Table 1 (continued)**

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| 10b | | Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling) | N/A |
| 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 | N/A |
| Blinding: | | | |
| 11a | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how | | N/A |
| 11b | If relevant, description of the similarity of interventions | | N/A |
| Statistical methods: | | | |
| 12a | Statistical methods used to compare groups for primary and secondary outcomes | How clustering was taken into account | 9-13 |
| 12b | Methods for additional analyses, such as subgroup analyses and adjusted analyses | | 9-13 |
| **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 | N/A |
| 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 | N/A |
| Recruitment: | | | |
| 14a | Dates defining the periods of recruitment and follow-up | | N/A |
| 14b | Why the trial ended or was stopped | | N/A |
| 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 | N/A |
| 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 | N/A |
| 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 | N/A |
| 17b | For binary outcomes, presentation of both absolute and relative effect sizes is recommended | | N/A |
| Ancillary analyses: | | | |
| 18 | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory | | N/A |
| Harms: | | | |
| 19 | All important harms or unintended effects in each group (for specific guidance see CONSORT for harms106) | | N/A |
| **Discussion** | | | |
| Limitations: | | | |
| 20 | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses | | 13 |
| Generalisability: | | | |
| 21 | Generalisability (external validity, applicability) of the trial findings | Generalisability to clusters and/or individual participants (as relevant) | 13 |

**Table 1 (continued)**

| Section/topic and item No | Standard checklist item | Extension for cluster designs | Page No* |
|---|---|---|---|
| Interpretation: | | | |
| 22 | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence | | 13 |
| **Other information** | | | |
| Registration: | | | |
| 23 | Registration number and name of trial registry | | 4 |
| Protocol: | | | |
| 24 | Where the full trial protocol can be accessed, if available | | N/A |
| Funding: | | | |
| 25 | Sources of funding and other support (such as supply of drugs), role of funders | | 13 |

*Page numbers optional depending on journal requirements.

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|---|---|---|---|
| | | | |

**Extension of CONSORT for abstracts11 12 to 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 | X |
| Trial design | Description of the trial design (for example, parallel, cluster, non-inferiority) | | |
| Methods: | | | |
| Participants | Eligibility criteria for participants and the settings where the data were collected | Eligibility criteria for clusters | X |
| Interventions | Interventions intended for each group | | |
| Objective | Specific objective or hypothesis | Whether objective or hypothesis pertains to the cluster level, the individual participant level, or both | X |
| Outcome | Clearly defined primary outcome for this report | Whether the primary outcome pertains to the cluster level, the individual participant level or both | X |
| Randomisation | How participants were allocated to interventions | How clusters were allocated to interventions | |
| Blinding (masking) | Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment | | |
| Results: | | | |
| Numbers randomised | Number of participants randomised to each group | Number of clusters randomised to each group | |
| Recruitment | Trial status* | | |
| Numbers analysed | Number of participants analysed in each group | Number of clusters analysed in each group | |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision | Results at the cluster or individual level as applicable for each primary outcome | |
| Harms | Important adverse events or side effects | | |
| Conclusions | General interpretation of the results | | X |
| Trial registration | Registration number and name of trial register | | X |
| Funding | Source of funding | | X |

*Relevant to conference abstracts.