Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

<table>
<thead>
<tr>
<th>Section/Topic</th>
<th>Item No</th>
<th>Standard Checklist item</th>
<th>Extension for cluster designs</th>
<th>Page No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1a</td>
<td></td>
<td>Identification as a randomised trial in the title</td>
<td>Identification as a cluster randomised trial in the title</td>
<td>p. 1 manuscript</td>
</tr>
<tr>
<td>1b</td>
<td></td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
<td>See table 2</td>
<td>p. 2 manuscript</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2a</td>
<td></td>
<td>Scientific background and explanation of rationale</td>
<td>Rationale for using a cluster design</td>
<td>p. 3-4 manuscript</td>
</tr>
</tbody>
</table>
| 2b                   |         | Specific objectives or hypotheses                                                         | Whether objectives pertain to the cluster level, the individual participant level or both       | p. 4 manuscript  
|                      |         |                                                                                          |                                                                                                | p. 4 protocol |
| **Methods**          |         |                                                                                          |                                                                                                |         |
| 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         | p. 4-6 manuscript  
|                      |         |                                                                                          |                                                                                                | p. 2-3 protocol |
| 3b                   |         | Important changes to methods after trial commencement (such as eligibility criteria), with reasons |                                                                                                  |         |
| **Participants**     |         |                                                                                          |                                                                                                |         |
| 4a                   |         | Eligibility criteria for participants                                                     | Eligibility criteria for clusters                                                               | p. 5 manuscript  
|                      |         |                                                                                          |                                                                                                | p. 2-3 protocol |
| 4b                   |         | Settings and locations where the data were collected                                      |                                                                                                  | p. 6 manuscript  
|                      |         |                                                                                          |                                                                                                | p. 3 protocol |
| **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     | p. 5-6 manuscript  
<p>|                      |         |                                                                                          |                                                                                                | p. 5 protocol |
| <strong>Outcomes</strong> | 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 | p. 6-7 manuscript p. 5 protocol |
| | 6b | Any changes to trial outcomes after the trial commenced, with reasons |
| <strong>Sample size</strong> | 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 |
| | 7b | When applicable, explanation of any interim analyses and stopping guidelines | p. 7 manuscript p. 5 protocol |
| <strong>Randomisation:</strong> | | | |
| <strong>Sequence generation</strong> | 8a | Method used to generate the random allocation sequence | p. 6 manuscript p. 3 protocol |
| | 8b | Type of randomisation; details of any restriction (such as blocking and block size) | Details of stratification or matching if used | p. 6 manuscript p. 3 protocol |
| <strong>Allocation concealment mechanism</strong> | 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 | p. 6 manuscript p. 3 protocol |
| <strong>Implementation</strong> | 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 | p. 6 manuscript p. 2-3 protocol |</p>
<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>enrolled clusters, and who assigned clusters to interventions</td>
<td></td>
</tr>
<tr>
<td>10b</td>
<td>Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete enumeration, random sampling)</td>
</tr>
<tr>
<td>10c</td>
<td>From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation</td>
</tr>
</tbody>
</table>

### Blinding

<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>11a</td>
<td>If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how</td>
</tr>
<tr>
<td>11b</td>
<td>If relevant, description of the similarity of interventions</td>
</tr>
</tbody>
</table>

### Statistical methods

<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>12a</td>
<td>Statistical methods used to compare groups for primary and secondary outcomes</td>
</tr>
<tr>
<td>12b</td>
<td>Methods for additional analyses, such as subgroup analyses and adjusted analyses</td>
</tr>
</tbody>
</table>

### Results

<table>
<thead>
<tr>
<th>Column</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>13a</td>
<td>For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome</td>
</tr>
<tr>
<td>Section</td>
<td>Item</td>
</tr>
<tr>
<td>---------</td>
<td>------</td>
</tr>
<tr>
<td>Recruitment</td>
<td>14a</td>
</tr>
<tr>
<td>Recruitment</td>
<td>14b</td>
</tr>
<tr>
<td>Baseline data</td>
<td>15</td>
</tr>
<tr>
<td>Baseline data</td>
<td>16</td>
</tr>
<tr>
<td>Outcomes and estimation</td>
<td>17a</td>
</tr>
<tr>
<td>Outcomes and estimation</td>
<td>17b</td>
</tr>
<tr>
<td>Ancillary analyses</td>
<td>18</td>
</tr>
<tr>
<td>Harms</td>
<td>19</td>
</tr>
<tr>
<td>Discussion</td>
<td>20</td>
</tr>
</tbody>
</table>

**Figure 2** manuscript

**p. 6 manuscript**

**p. 2 protocol**

**Table 1** manuscript

**p. 10 manuscript**

**p. 3 protocol**

**p. 8-12 manuscript**

**p. 12-14 manuscript**

**p. 14-16 manuscript**
imprecision, and, if relevant, multiplicity of analyses

<table>
<thead>
<tr>
<th><strong>Generalisability</strong></th>
<th>21</th>
<th>Generalisability (external validity, applicability) of the trial findings</th>
<th>Generalisability to clusters and/or individual participants (as relevant)</th>
<th>p. 14-18 manuscript</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interpretation</strong></td>
<td>22</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
<td></td>
<td>p. 14-18 manuscript</td>
</tr>
</tbody>
</table>

**Other information**

<table>
<thead>
<tr>
<th><strong>Registration</strong></th>
<th>23</th>
<th>Registration number and name of trial registry</th>
<th>p. 2 manuscript</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Protocol</strong></td>
<td>24</td>
<td>Where the full trial protocol can be accessed, if available</td>
<td>p. 18 manuscript</td>
</tr>
<tr>
<td><strong>Funding</strong></td>
<td>25</td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
<td>p. 18-19 manuscript</td>
</tr>
</tbody>
</table>

*Note: page numbers optional depending on journal requirements*
Table 2: Extension of CONSORT for abstracts\(^1\) to reports of cluster randomised trials

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

\(^1\) Relevant to Conference Abstracts
REFERENCES

