**Checklist for abstracts for randomised trials: items to include1**

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| Paper ref no. |

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| **ITEM** | **DESCRIPTION** | **REPORTED** |
| Title | Identification of study as randomised |  |
| Trial design | Description of trial design (e.g. parallel, cluster, crossover) |  |
| Methods |  |  |
| Participants | Eligibility criteria for participants and the setting where the data were collected |  |
| Interventions | Interventions intended for each group |  |
| Objectives | Specific objective or hypothesis |  |
| Outcomes | Clearly defined primary outcome for this report and when it was assessed |  |
| Randomisation | How participants were allocated to interventions and details of allocation concealment e.g. allocation by central office; sequentially numbered, opaque, sealed envelopes |  |
| Blinding (masking) | Whether or not participants, caregivers, and those assessing the outcomes were blinded to group assignment. Avoid use of terms such as ‘single’ and ‘double’ blinded as they are not always understood |  |
| Results |  |  |
| Number randomised | Number of participants randomised to each group |  |
| Number analysed | Number of participants analysed in each group |  |
| Outcome | For the primary outcome, a result for each group and the estimated effect size and its precision |  |
| Harms | Important adverse (or unexpected) effects or side effects |  |
| Conclusions | General interpretation of the results |  |
| Trial registration2 | Registration no. and name of trial register |  |
| Funding | Source of funding |  |
| Flow diagram3 | Includes: Enrolment/Allocation/Follow-up/Analysis |  |

**Notes:**

1. For examples of abstracts formatted in this way, see:

<http://www.consort-statement.org/mod_product/uploads/CONSORT%20for%20Abstracts%20-%20checklist%20examples.pdf>

2. Acceptable trial registers are:

* Australian New Zealand Clinical Trials Registry ([www.anzctr.org.au](http://www.anzctr.org.au))
* ClinicalTrials.gov ([www.clinicaltrials.gov](http://www.clinicaltrials.gov))
* International Standard Randomised Controlled Trial Number Register (<http://isrctn.org>)
* UMIN Clinical Trials Registry ([www.umin.ac.jp/ctr/index.htm](http://www.umin.ac.jp/ctr/index.htm))
* Nederlands Trial Register ([www.trialregister.nl/](http://www.trialregister.nl/trialreg/index.asp))
* or any registries accepted by WHO as primary registers (see <http://www.who.int/ictrp/network/primary_registers/en/index.html/>)

3. For outline flow diagram, see:

<http://www.consort-statement.org/index.aspx?o=1077>