

Checklist for authors submitting reports of randomised controlled trials to the *BDJ*

Instructions for authors

You should complete the check list (Table 1) and flow diagram (fig. 1) and submit both with your manuscript as these are essential for the review process. These guidelines should assist you and your reviewers in assessing the manuscript. Please note the additional subheadings that should appear in the manuscript and the flow diagram which should appear as a figure within the manuscript. For more information, please consult the original article, Begg C, Cho M, Eastwood S, *et al*. Improving the quality of reporting of randomised controlled trials: the CONSORT statement. *JAMA*, 1996; 276: 637-639. (Full text article available on JAMA website at: <http://www.ama-assn.org/public/journals/jama/jamahome.htm>)

Preparing reports of randomised controlled trials

The checklist (*JAMA* 1999; 281: 17) should be completed and submitted with the manuscript. In addition, a flow diagram illustrating the progress of patients throughout the trial should be included as a figure in the manuscript (fig. 1). The checklist and flow diagram will be reviewed along with the manuscript.

Note: The checklist can be found at <http://www.bdj.co.uk>

Table 1 First author's name and manuscript title

| Heading | Subheading | Descriptor | Was it reported? Yes or No | If Yes, what page no.? | | |
|--|--|--|---|---|-------|-------|
| <i>Title</i> <i>Abstract</i> <i>Introduction</i> | | 1. Identify the study as a randomised trial. | | | | |
| | | 2. Use a structured format. | | | | |
| | | 3. State prospectively defined hypothesis, clinical objectives, and planned subgroup or covariate analyses. | | | | |
| <i>Methods</i> | <i>Protocol</i> | <i>Describe:</i> | | | | |
| | | 4. Planned study population, together with inclusion/exclusion criteria. | | | | |
| | | 5. Planned interventions and their timing. | | | | |
| | | 6. Primary and secondary outcome measure(s) and the minimum important difference(s), and how the target sample size was projected. | | | | |
| | | 7. Rationale and methods for statistical analyses, detailing main comparative analyses and whether they were completed on an intention-to-treat basis. | | | | |
| | | 8. Prospectively defined stopping rules (if warranted). | | | | |
| | | <i>Assignment</i> | <i>Describe:</i> | | | |
| | | | 9. Unit of randomisation (eg individual, cluster, geographic). | | | |
| | <i>Masking (Blinding)</i> | 10. Method used to generate the allocation schedule. | | | | |
| | | 11. Method of allocation concealment and timing of assignment. | | | | |
| | | 12. Method to separate the generator from the executor of assignment. | | | | |
| | | 13. Describe mechanism (eg, capsules, tablets); similarity of treatment characteristics (eg appearance, taste); allocation schedule control (location of code during trial and when broken); and evidence for successful masking (blinding) among participants, person doing intervention, outcome assessors, and data analysts. | | | | |
| | | <i>Results</i> | <i>Participant Flow and Follow-up</i> | 14. Provide a trial profile as a Figure in the manuscript (see flow diagram summarizing participant flow, numbers and timing of randomization assignment, interventions, and measurements for each randomised group). | | |
| <i>Analysis</i> | 15. State estimated effect of intervention on primary and secondary outcome measures, including a point estimate and measure of precision (confidence interval)..... | | | | | |
| | 16. State results in absolute numbers when feasible (eg 10/20, not 50%). | | | | | |
| | 17. Present summary data and appropriate descriptive and inferential statistics in sufficient detail to permit alternative analyses and replication. | | | | | |
| | 18. Describe prognostic variables by treatment group and any attempt to adjust for them. | | | | | |
| | 19. Describe protocol deviations from the study as planned, together with the reasons. | | | | | |
| | <i>Discussion</i> | | 20. State specific interpretation of study findings, including a discussion of internal bias (the degree to which the trial design, conduct analysis and presentation have minimised or avoided biased comparisons of the interventions under evaluation) and external bias (the precision and extent to which it is possible to generalise the results of the trial to other settings) | | | |
| | | | 21. State general interpretation of the data in light of the totality of the available evidence. | | | |

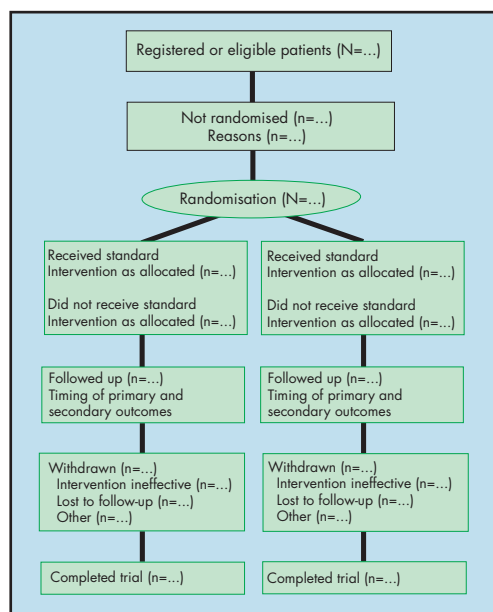


Fig. 1 Profile of randomised controlled trial

Please note: Both the general guidelines for authors and these CONSORT guidelines are available on the *BDJ* website at <http://www.bdj.co.uk>