Endorsement of the CONSORT statement by high impact medical journals: survey of instructions for authors

Douglas G Altman for the CONSORT Group

The CONSORT (Consolidated Standards of Reporting Trials) statement of 1996, updated in 2001, gives recommendations for reporting randomised controlled trials and has been endorsed by the World Association of Medical Editors, the International Committee of Medical Journal Editors (ICMJE), and the Council of Science Editors. Studies indicate that it has helped to improve the quality of reporting of trials. I sought to determine the extent to which leading medical journals had incorporated the CONSORT recommendations into their instructions for authors.

Methods and results

Using citation impact factors for 2001, I identified the top five journals from each of 33 medical specialties and the top 15 journals for general and internal medicine. I excluded selected journals that did not publish clinical research (based on explicit statement, inspection of journal contents, or PubMed search) and replaced them by the next on the list. The final sample of 167 journals was obtained after examining 252 journals. Thirteen journals represented two specialties.

Between January and May 2003 I examined the instructions for authors on each journal's website and extracted all text mentioning CONSORT or other publications relevant to randomised trials. I also sought any mention of the ICMJE's Uniform Requirements for Manuscripts Submitted to Biomedical Journals. CONSORT was mentioned in the instructions of 36 (22%) journals (see bmj.com), more often in general and internal medicine journals (8/15; 53%) than in specialty journals (28/152; 18%). However, 9/36 journals referred only to the obsolete 1996 statement, whereas the other 27 journals (16% of the sample) referred to the latest version, gave the web address (www.consort-statement.org), or both. No journal cited alternative reporting recommendations for randomised controlled trials.

Of the 167 journals, 72 (43%) referred to the ICMJE guidelines. Another incorporated much of the ICMJE text without attribution. Eleven of these journals cited the ICMJE guidelines only for particular issues, mostly reference style or authorship.

Only 24/72 journals gave the address; 4 others referred to versions on the websites of the CMAJ or the Lancet. Most of the remaining 44 journals cited an obsolete journal publication: one from 1999, 30 from 1997, five from 1991, two from 1988, and two from 1982. Four journals gave no reference. Journals that referred to CONSORT were much more likely to refer to the ICMJE guidelines (26/36; 72%) than those journals that did not (46/131; 35%).

Comment

In 2003, 36/167 (22%) of high impact medical journals referred to CONSORT in their advice to authors. The uptake of CONSORT by leading journals is encouraging, but 11/36 referred only to a superseded version of CONSORT. Also, many used ambiguous language regarding what was expected or failed to cite CONSORT appropriately. Journals should be more explicit in their expectations of authors and ensure the accuracy of their instructions to authors.
Journals supporting CONSORT should state unambiguously what they expect from authors.

In 2003, many journals gave out of date citations for both CONSORT and the ICMJE guidelines. This carelessness sets a poor example for authors. Journals should be more vigilant regarding the information in their instructions to authors, should be explicit in their expectations of adherence to specific recommendations, and should cite the web address to ensure that the latest versions are obtained along with any extensions.

I thank for helpful comments on an earlier draft from members of the CONSORT Group: Patrick Bossuyt, Frank Davidoff, Diana Elbourne, Stephen Evans, Peter Gotzsche, David Grimes, Barbara Hawkins, John Ioannidis, Tom Lang, David Moher, Cynthia Mulrow, Roberta Scherer, and Kenneth Schulz.

Contributors: DGA is the sole contributor.

Funding: DGA is employed by Cancer Research UK, but this study had no explicit funding.

Competing interests: DGA is a member of the CONSORT Group.

Ethical approval: Not needed.


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(Accepted 2 March 2005)

Adequacy and reporting of allocation concealment: review of recent trials published in four general medical journals

Catherine Hewitt, Seokyung Hahn, David J Torgerson, Judith Watson, J Martin Bland

In randomised controlled trials, allocation concealment (separating the process of randomisation from the recruitment of participants) is important for rigorously designed trials. In 1996 many major medical journals adopted the CONSORT statement (whereby researchers have to include a short checklist of essential items and a flow diagram when reporting trials), and this move encouraged the reporting of allocation concealment. We reviewed the prevalence of adequate allocation concealment and its association with the statistical significance of trial results.

Methods and results

We searched by hand four general medical journals (the BMJ, JAMA, the Lancet, and the New England Journal of Medicine) to identify randomised controlled trials published from January 2002 to December 2002. We included articles if the authors reported that participants were randomised and if the trial was published as a full report with the results of the main analyses. We categorised articles according to whether allocation concealment was adequate (the person who executed the allocation sequence was different from the person who recruited participants), inadequate (the person who recruited participants also executed the allocation sequence), or unclear (the article failed to describe how the researchers concealed the allocation). We considered the widely used “sealed envelope” method to be inadequate unless performed by an independent third party. We used a kernel density plot to compare the P values of trials that used adequate concealment methods with those that used inadequate methods; we used P values because these were readily available across most of the trials, which used different statistical methods and outcome measures. Our statistical analyses adjusted for clustering effects by journal.

Among the 234 trials that met the inclusion criteria, allocation concealment was adequate in 132 (56%) and inadequate in 41 (18%); in 61 (20%) the concealment method was unclear. Of the trials whose allocation concealment was considered adequate, 118 used independent allocation (which included using a telephone, fax machine, or pager to a randomisation service); five used sealed envelopes opened by a third party; eight used a computer; and one used a combination of adequate methods. Of the 41 trials whose allocation concealment was inadequate, 39 used sealed envelopes, one selected a card from a pile, and one added the name of the next participant to the randomisation list.

This article was posted on bmj.com on 10 March 2005: http://bmj.com/cgi/doi/10.1136/bmj.330.7499.1056

BMJ: first published as 10.1136/bmj.330.7499.1056 on 5 May 2005. Downloaded from http://www.bmj.com on 25 April 2022 by guest. Protected by copyright.