

CONSORT for reporting randomised trials in journal and conference abstracts



In 2006, Arthur Amman, President of Global Strategies for HIV Prevention, made a disquieting remark: "I recently met a physician from southern Africa, engaged in perinatal HIV prevention, whose primary access to information was abstracts posted on the internet. Based on a single abstract, they had altered their perinatal HIV prevention program from an effective therapy to one with lesser efficacy. Had they read the full text article they would have undoubtedly realized that the study results were based on short-term follow-up, a small pivotal group, incomplete data, and unlikely to be applicable to their country situation. Their decision to alter treatment based solely on the abstract's conclusions may have resulted in increased perinatal HIV transmission."¹

For clinical trials, clear, transparent, and sufficiently detailed abstracts of journal articles and conference abstracts are important because readers often base their assessment of a trial on such information. Some use an abstract to decide whether to seek more information about a trial. However, in some parts of the world, health professionals often have access to the abstracts only, so health-care decisions are made on the basis of abstracts of randomised trials.¹ When a trial is reported at a conference, the abstract might provide the only permanent information accessible to most readers.²

The CONSORT Statement, first published in 1996³ and updated in 2001,⁴ provides recommendations for reporting randomised trials in health-care journals and elsewhere. CONSORT has been endorsed by the World Association of Medical Editors, the International Committee of Medical Journal Editors (ICMJE), and the Council of Science Editors. Currently, the CONSORT Statement provides limited guidance about preparing abstracts and, while it encourages the use of a structured format, this is not a formal requirement. The ICMJE Uniform Requirements⁵ also provide limited guidance on the format of abstracts for journal articles.

We believe that journals and conference organisers should provide specific instructions about the key elements of a trial that authors should report, within the space limitations of an abstract (typically, 250–300 words). Our preliminary work shows that all the checklist items can be fitted within such word limits.

Yet a study that examined 35 journals' instructions for authors found that only 4% of the text was devoted to the content or format of the abstract.⁶ When key details about a trial are lacking, it is difficult to assess the validity of the results and their applicability.

In collaboration with members of the CONSORT Group, we have extended the current CONSORT Statement to develop a checklist of essential items which authors should include when reporting the main results of a randomised trial in a journal or conference abstract. We recognise that many journals have developed their own structure for reporting abstracts. Our intention is not to suggest changes to these formats, but to recommend what information should be reported within them when describing randomised trials.

In developing this checklist we generated a list of items from existing tools for quality assessment and

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Item	Description
Title	Identification of the study as randomised
Authors*	Contact details for the corresponding author
Trial design	Description of the trial design (eg, parallel, cluster, non-inferiority)
Methods	
Participants	Eligibility criteria for participants and the settings where the data were collected
Interventions	Interventions intended for each group
Objective	Specific objective or hypothesis
Outcome	Clearly defined primary outcome for this report
Randomisation	How participants 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
Recruitment	Trial status
Numbers 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 events or side-effects
Conclusions	General interpretation of the results
Trial registration	Registration number and name of trial register
Funding	Source of funding
*For conference abstracts.	
Table: Items to include when reporting randomised trials in journal or conference abstracts⁷	

from empirical evidence. We used a modified Delphi consensus method to select and reduce the number of possible items. Participants with an interest in reporting randomised trials, abstracts' structures, or both, were invited to participate in an internet-based survey and rate the importance of suggested items. These results were presented at a meeting of the CONSORT Group in January, 2007, and items were discussed for inclusion in the final checklist. The checklist was then revised to ensure it reflected discussions held during and after the meeting.

Checklist items (table⁷) for reporting an abstract of a randomised trial include: details of the trial's objectives; trial design (eg, method of allocation, blinding); participants in the trial (ie, description, numbers randomised and analysed); interventions intended for each randomised group and their effect on primary efficacy outcomes and harms; the trial's conclusions; the trial's registration name and number; and source of funding. We strongly recommend the use of structured abstracts for reporting randomised trials.⁸ We also recommend this checklist is used in conjunction with its explanatory document, which includes examples of good reporting, rationale, and evidence, when available, for the inclusion of the items.⁹

As for the revised CONSORT Statement, we have focused on reporting of parallel-group randomised trials. There may well be instances where different types of trial information, such as composite outcomes, or different designs (such as cluster randomisation or non-inferiority and equivalence trials), will require additional information. Extensions or adaptations to the checklist may be warranted for different situations, as has been done for the CONSORT Statement for full reports.^{10,11}

We encourage journals and conference organisers to endorse the use of CONSORT for abstracts by modifying their instructions to authors and drawing attention to the checklist. We hope that this extension to the CONSORT Statement will help authors to provide the necessary

detail and clarity in abstracts which will allow readers to assess the validity and applicability of randomised trial results. Examples of reports of abstracts that use this checklist are provided on the CONSORT website.⁷

*Sally Hopewell, Mike Clarke, David Moher, Elizabeth Wager, Philippa Middleton, Douglas G Altman, Kenneth F Schulz, and the CONSORT Group

UK Cochrane Centre, Summertown Pavilion, Oxford OX2 7LG, UK (SH, MC); School of Nursing and Midwifery, Trinity College, Dublin, Ireland (MC); Chalmers Research Group, Children's Hospital of Eastern Ontario Research Institute, Ottawa, ON, Canada (DM); Department of Epidemiology and Community Medicine, Faculty of Medicine, University of Ottawa, Ottawa, ON, Canada (DM); Sideview, Princes Risborough, UK (EW); Discipline of Obstetrics and Gynaecology, University of Adelaide, Adelaide, SA, Australia (PM); Centre for Statistics in Medicine, Wolfson College, Oxford, UK (SH, DGA); and Family Health International, Research Triangle Park, Durham, NC, USA (KFS)
shopewell@cochrane.co.uk

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