CONSORT 2010 Statement: updated guidelines for reporting parallel group randomised trials

Kenneth F Schulz, Douglas G Altman, David Moher, for the CONSORT Group

Introduction
Randomised controlled trials, when appropriately designed, conducted, and reported, represent the gold standard in evaluating health-care interventions. However, randomised trials can yield biased results if they lack methodological rigor. To assess a trial accurately, readers of a published report need complete, clear, and transparent information on its methodology and findings. Unfortunately, attempted assessments frequently fail because authors of many trial reports neglect to provide lucid and complete descriptions of that critical information.2-4 That lack of adequate reporting fuelled the development of the original CONSORT (Consolidated Standards of Reporting Trials) statement in 1996 and its revision 5 years later.5-8 While those statements improved the reporting quality for some randomised controlled trials,9-10 many trial reports still remain inadequate.2 Furthermore, new methodological evidence and additional experience has accumulated since the last revision in 2001. Consequently, we organised a CONSORT Group meeting to update the 2001 statement.5-8 We introduce here the result of that process, CONSORT 2010.

Intent of CONSORT 2010
The CONSORT 2010 Statement is this paper including the 25 item checklist in the table and flow diagram (figure). It provides guidance for reporting all randomised controlled trials, but focuses on the most common design type—individually randomised, two group, parallel trials. Other trial designs, such as cluster randomised trials and non-inferiority trials, require varying amounts of additional information. CONSORT extensions for these designs,11,12 and other CONSORT products, can be found through the CONSORT website. Along with the CONSORT statement, we have updated the explanation and elaboration article,13 which explains the inclusion of each checklist item, provides methodological background, and gives published examples of transparent reporting.

Diligent adherence by authors to the checklist items facilitates clarity, completeness, and transparency of reporting. Explicit descriptions, not ambiguity or omission, best serve the interests of all readers. Note that the CONSORT 2010 Statement does not include recommendations for designing, conducting, and analysing trials. It solely addresses the reporting of what was done and what was found.

Nevertheless, CONSORT does indirectly affect design and conduct. Transparent reporting reveals deficiencies in research if they exist. Thus, investigators who conduct inadequate trials, but who must transparently report, should not be able to pass through the publication process without revelation of their trial’s inadequacies. That emerging reality should provide impetus to improved trial design and conduct in the future, a secondary indirect goal of our work. Moreover, CONSORT can help researchers in designing their trial.

Background to CONSORT
Efforts to improve the reporting of randomised controlled trials accelerated in the mid-1990s, spurred partly by methodological research. Researchers had shown for many years that authors reported such trials poorly, and empirical evidence began to accumulate that some poorly conducted or poorly reported aspects of trials were associated with bias.14 Two initiatives aimed at developing reporting guidelines culminated in one of us (DM) and Drummond Rennie organising the first CONSORT statement in 1996.1 Further methodological research on similar topics reinforced earlier findings15 and fed into the revision of 2001.4-8 Subsequently, the expanding body of methodological research informed the refinement of CONSORT 2010. More than 700 studies comprise the CONSORT database (located on the CONSORT website), which provides the empirical evidence to underpin the CONSORT initiative.

Figure: Flow diagram of the progress through the phases of a parallel randomised trial of two groups

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For more on CONSORT see http://www.consort-statement.org
Indeed, CONSORT Group members continually monitor the literature. Information gleaned from these efforts provides an evidence base on which to update the CONSORT statement. We add, drop, or modify items based on that evidence and the recommendations of the CONSORT Group, an international and eclectic group of professional researchers, methodologists, and practitioners with experience in conducting and reporting clinical trials.

<table>
<thead>
<tr>
<th>Section/topic</th>
<th>Item number</th>
<th>Checklist item</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td>1a</td>
<td>Identification as a randomised trial in the title</td>
</tr>
<tr>
<td></td>
<td>1b</td>
<td>Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Background and objectives</td>
<td>2a</td>
<td>Scientific background and explanation of rationale</td>
</tr>
<tr>
<td></td>
<td>2b</td>
<td>Specific objectives or hypotheses</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trial design</td>
<td>3a</td>
<td>Description of trial design (such as parallel, factorial) including allocation ratio</td>
</tr>
<tr>
<td></td>
<td>3b</td>
<td>Important changes to methods after trial commencement (such as eligibility criteria), with reasons</td>
</tr>
<tr>
<td>Participants</td>
<td>4a</td>
<td>Eligibility criteria for participants</td>
</tr>
<tr>
<td></td>
<td>4b</td>
<td>Settings and locations where the data were collected</td>
</tr>
<tr>
<td>Interventions</td>
<td>5</td>
<td>The interventions for each group with sufficient details to allow replication, including how and when they were actually administered</td>
</tr>
<tr>
<td>Outcomes</td>
<td>6a</td>
<td>Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed</td>
</tr>
<tr>
<td></td>
<td>6b</td>
<td>Any changes to trial outcomes after the trial commenced, with reasons</td>
</tr>
<tr>
<td>Sample size</td>
<td>7a</td>
<td>How sample size was determined</td>
</tr>
<tr>
<td></td>
<td>7b</td>
<td>When applicable, explanation of any interim analyses and stopping guidelines</td>
</tr>
<tr>
<td><strong>Randomisation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sequence generation</td>
<td>8a</td>
<td>Method used to generate the random allocation sequence</td>
</tr>
<tr>
<td></td>
<td>8b</td>
<td>Type of randomisation; details of any restriction (such as blocking and block size)</td>
</tr>
<tr>
<td>Allocation concealment</td>
<td>9</td>
<td>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</td>
</tr>
<tr>
<td>mechanism</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Implementation</td>
<td>10</td>
<td>Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions</td>
</tr>
<tr>
<td>Blinding</td>
<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></td>
<td>11b</td>
<td>If relevant, description of the similarity of interventions</td>
</tr>
<tr>
<td>Statistical methods</td>
<td>12a</td>
<td>Statistical methods used to compare groups for primary and secondary outcomes</td>
</tr>
<tr>
<td></td>
<td>12b</td>
<td>Methods for additional analyses, such as subgroup analyses and adjusted analyses</td>
</tr>
<tr>
<td><strong>Results</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Participant flow (a diagram is strongly recommended)</td>
<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></td>
<td>13b</td>
<td>For each group, losses and exclusions after randomisation, together with reasons</td>
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<tr>
<td>Recruitment</td>
<td>14a</td>
<td>Dates defining the periods of recruitment and follow-up</td>
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<tr>
<td></td>
<td>14b</td>
<td>Why the trial ended or was stopped</td>
</tr>
<tr>
<td>Baseline data</td>
<td>15</td>
<td>A table showing baseline demographic and clinical characteristics for each group</td>
</tr>
<tr>
<td>Numbers analysed</td>
<td>16</td>
<td>For each group, number of participants (denominator) included in each analysis, and whether the analysis was by original assigned groups</td>
</tr>
<tr>
<td>Outcomes and estimation</td>
<td>17a</td>
<td>For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% CI)</td>
</tr>
<tr>
<td></td>
<td>17b</td>
<td>For binary outcomes, presentation of both absolute and relative effect sizes is recommended</td>
</tr>
<tr>
<td>Ancillary analyses</td>
<td>18</td>
<td>Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing prespecified from exploratory</td>
</tr>
<tr>
<td>Harms</td>
<td>19</td>
<td>All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)</td>
</tr>
<tr>
<td><strong>Discussion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Limitations</td>
<td>20</td>
<td>Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses</td>
</tr>
<tr>
<td>Generalisability</td>
<td>21</td>
<td>Generalisability (external validity, applicability) of the trial findings</td>
</tr>
<tr>
<td>Interpretation</td>
<td>22</td>
<td>Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registration</td>
<td>23</td>
<td>Registration number and name of trial registry</td>
</tr>
<tr>
<td>Protocol</td>
<td>24</td>
<td>Where the full trial protocol can be accessed, if available</td>
</tr>
<tr>
<td>Funding</td>
<td>25</td>
<td>Sources of funding and other support (such as supply of drugs), role of funders</td>
</tr>
</tbody>
</table>

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming; for those and for up-to-date references relevant to this checklist, see http://www.consort-statement.org.

Table: CONSORT 2010 checklist of information to include when reporting a randomised trial*
The CONSORT Executive then drafted an updated explanation and elaboration manuscript, with assistance from other members of the larger group. The substance of the 2007 CONSORT meeting provided the material for the update. The updated explanation and elaboration manuscript was distributed to the entire group for additions, deletions, and changes. That final iterative process converged to the CONSORT 2010 Explanation and Elaboration.\(^9\)

### Changes in CONSORT 2010

The revision process resulted in evolutionary, not revolutionary, changes to the checklist (table), and the flow diagram was not modified except for one word (figure). Moreover, because other reporting guidelines augmenting the checklist refer to item numbers, we kept the existing items under their previous item numbers except for some renumbering of items 2–5.

#### Panel 1: Noteworthy general changes in CONSORT 2010 Statement

- We simplified and clarified the wording, such as in items 1, 8, 10, 13, 15, 16, 18, 19, and 21.
- We improved consistency of style across the items by removing the imperative verbs that were in the 2001 version.
- We enhanced specificity of appraisal by breaking some items into sub-items. Many journals expect authors to complete a CONSORT checklist indicating where in the manuscript the items have been addressed. Experience with the checklist noted pragmatic difficulties when an item comprised multiple elements. For example, item 4 addresses eligibility of participants and the settings and locations of data collection. With the 2001 version, an author could provide a page number for that item on the checklist, but might have reported only eligibility in the paper, for example, and not reported the settings and locations. CONSORT 2010 relieves obfuscations and forces authors to provide page numbers in the checklist for both eligibility and settings.

#### Panel 2: Noteworthy specific changes in CONSORT 2010 Statement

- **Item 1 (Title and abstract)**
  We added a sub-item (b) on providing a structured summary of trial design, methods, results, and conclusions and referenced the CONSORT for abstracts article.\(^10\)
- **Introduction**
  We added a new sub-item (b; formerly item 5 in CONSORT 2001) on specific objectives or hypotheses.
- **Methods, trial design**
  We added a new item including sub-item (a) to clarify the basic trial design (such as parallel group, crossover, cluster) and the allocation ratio.
  We added a new sub-item (b) that addresses any important changes to methods after trial commencement, with a discussion of reasons.
- **Methods, participants**
  Formerly item 3 in CONSORT 2001.
- **Methods, interventions**
  Formerly item 4 in CONSORT 2001. We encouraged greater specificity by stating that descriptions of interventions should include sufficient details to allow replication.\(^3\)

(Continues on next page)
We added a sub-item on identifying any changes to the primary and secondary outcome (endpoint) measures after the trial started. This followed from empirical evidence that authors frequently provide analyses of outcomes in their published papers that were not the prespecified primary and secondary outcomes in their protocols, while ignoring their prespecified outcomes (that is, selective outcome reporting). We eliminated text on any methods used to enhance the quality of measurements.

Item 9 (Methods, randomisation, allocation concealment mechanism)
We reworded this to include mechanism in both the report topic and the descriptor to reinforce that authors should report the actual steps taken to ensure allocation concealment rather than simply report imprecise, perhaps banal, assurances of concealment.

Item 11 (Methods, blinding)
We added the specification of how blinding was done and, if relevant, a description of the similarity of interventions and procedures. We also eliminated text on “how the success of blinding (masking) was assessed” because of a lack of empirical evidence supporting the practice as well as theoretical concerns about the validity of any such assessment.

Item 12 (Methods, statistical methods)
We added that statistical methods should also be provided for analysis of secondary outcomes (a).

Item 14 (Results, recruitment)
Based on empirical research, we added a sub-item (b) on why the trial ended or was stopped.

Item 15 (Results, baseline data)
We specified “a table” to clarify that baseline and clinical characteristics of each group are most clearly expressed in a table.

Item 16 (Results, numbers analysed)
We replaced mention of intention-to-treat analysis, a widely misused term, by a more explicit request for information about retaining participants in their original assigned groups.

Item 17 (Results, outcomes and estimation)
For appropriate clinical interpretability, prevailing experience suggested the addition of (b) for binary outcomes, presentation of both relative and absolute effect sizes is recommended.

Item 19 (Results, harms)
We included a reference to the CONSORT paper on harms.

Item 20 (Discussion, limitations)
We changed the topic from “Interpretation” and supplanted the prior text with a sentence focusing on the reporting of sources of potential bias and imprecision.

Item 22 (Discussion, interpretation)
We changed the topic from “Overall evidence”. Indeed, we understand that authors should be allowed leeway for interpretation under this nebulous heading. However, the CONSORT Group expressed concerns that conclusions in papers frequently misrepresented the actual analytical results and that harms were ignored or marginalised. Therefore, we changed the checklist item to include the concepts of results matching interpretations and of benefits being balanced with harms.

We added additional items either as a sub-item under an existing item, an entirely new item number at the end of the checklist, or (with item 3) an interjected item into a renumbered segment. We have summarised the noteworthy general changes in panel 1 and specific changes in panel 2. The CONSORT website contains a side by side comparison of the 2001 and 2010 versions.

Implications and limitations
We developed CONSORT 2010 to assist authors in writing reports of randomised controlled trials, editors and peer reviewers in reviewing manuscripts for publication, and readers in critically appraising published articles. The CONSORT 2010 Explanation and Elaboration provides elucidation and context to the checklist items. We strongly recommend using the explanation and elaboration in conjunction with the checklist to foster complete, clear, and transparent reporting and aid appraisal of published trial reports.

CONSORT 2010 focuses predominantly on the two group, parallel randomised controlled trial, which accounts for over half of trials in the literature. Most of the items from the CONSORT 2010 Statement, however, pertain to all types of randomised trials. Nevertheless, some types of trials or trial situations dictate the need for additional information in the trial report. When in doubt, authors, editors, and readers should consult the CONSORT website for any CONSORT extensions, expansions (amplifications), implementations, or other guidance that may be relevant.

The evidence based approach we have used for CONSORT also served as a model for development of other reporting guidelines, such as for reporting systematic reviews and meta-analyses of studies evaluating interventions, diagnostic studies, and observational studies. The explicit goal of all these initiatives is to improve reporting. The Enhancing the Quality and Transparency of Health Research (EQUATOR) Network will facilitate development of reporting guidelines and help disseminate the guidelines.

With CONSORT 2010, we again intentionally declined to produce a rigid structure for the reporting of randomised trials. Indeed, SORT tried a rigid format, and it failed in a pilot run with an editor and authors. Consequently, the format of articles should abide by journal style, editorial directions, the traditions of the research field addressed, and, where possible, author preferences. We do not wish to standardise the structure of reporting. Authors should simply address checklist items somewhere in the article, with ample detail and lucidity. That stated, we think that manuscripts benefit from frequent subheadings within the major sections, especially the methods and results sections.

CONSORT urges completeness, clarity, and transparency of reporting, which simply reflects the actual
trial design and conduct. However, as a potential drawback, a reporting guideline might encourage some authors to report fictitiously the information suggested by the guidance rather than what was actually done. Authors, peer reviewers, and editors should vigilantly guard against that potential drawback and refer, for example, to trial protocols, to information on trial registers, and to regulatory agency websites. Moreover, the CONSORT 2010 Statement does not include recommendations for designing and conducting randomised trials. The items should elicit clear pronouncements of how and what the authors did, but do not contain any judgments on how and what the authors should have done. Thus, CONSORT 2010 is not intended as an instrument to evaluate the quality of a trial. Nor is it appropriate to use the checklist to construct a “quality score”.

Nevertheless, we suggest that researchers begin trials with their end publication in mind. Poor reporting allows authors, intentionally or inadvertently, to escape scrutiny of any weak aspects of their trials. However, with wide adoption of CONSORT by journals and editorial groups, most authors should have to report transparently all important aspects of their trial. The ensuing scrutiny rewards well conducted trials and penalises poorly conducted trials. Thus, investigators should understand the CONSORT 2010 reporting guidelines before starting a trial as a further incentive to design and conduct their trials according to rigorous standards.

CONSORT 2010 supplants the prior version published in 2001. Any support for the earlier version accumulated from journals or editorial groups will automatically extend to this newer version, unless specifically requested otherwise. Journals that do not currently support CONSORT may do so by registering on the CONSORT website. If a journal supports or endorses CONSORT 2010, it should cite one of the original versions of CONSORT 2010, the CONSORT 2010 Explanation and Elaboration, and the CONSORT website in their instructions to authors. We suggest that authors who wish to cite CONSORT should cite this or another of the original journal versions of the CONSORT 2010 Statement, and, if appropriate, the CONSORT 2010 Explanation and Elaboration.11 All CONSORT material can be accessed through the original publishing journals or the CONSORT website. Groups or individuals who desire to translate the CONSORT 2010 Statement into other languages should first consult the CONSORT policy statement on the website.

We emphasise that CONSORT 2010 represents an evolving guideline. It requires perpetual reappraisal and, if necessary, modifications. In the future we will further revise the CONSORT material considering comments, criticisms, experiences, and accumulating new evidence. We invite readers to submit recommendations via the CONSORT website.

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Item 24 (Other information, protocol)
We added a new item on availability of the trial protocol. Empirical evidence suggests that authors often ignore, in the conduct and reporting of their trial, what they stated in the protocol.46 Hence, availability of the protocol can instigate adherence to the protocol before publication and facilitate assessment of adherence after publication.

Item 25 (Other information, funding)
We added a new item on funding. Empirical evidence points toward funding source sometimes being associated with estimated treatment effects.30

Contributors
KFS, DM, and DGA participated in meetings and regular conference calls, planned the CONSORT 2007 meeting at Montebello, developed the agenda, prepared background research, identified and invited participants, contributed to the CONSORT meeting, drafted the manuscript, and, after critical review by the CONSORT Group, finalised the text of the manuscript. Members of the CONSORT Group attended the meeting, except for those noted below, and provided input on and review of the revised checklist and text of this article. Some members also prepared background material.

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Contributors to CONSORT 2010 who did not attend the Montebello meeting: Mike Clarke (UK Cochrane Centre); Gordon Guyatt (McMaster University, Canada).

Conflicts of interest
Uniform disclosure of potential conflicts of interest: all authors have completed the ICMJE unified competing interest form at www.icmje.org/coi_disclosure.pdf (available from the corresponding author) and declare DM received grants for this work from Johnson & Johnson, BMJ, and American Society for Clinical Oncology; KFS and DGA received support for travel to meetings for this work from Johnson & Johnson, BMJ, and American Society for Clinical Oncology; KFS and DGA had travel expenses reimbursed by the EQUATOR Network; KFS has received honoraria for delivering educational presentations for the American Board of Obstetrics and Gynecology Foundation for Excellence in Women’s Health Care, Ortho-McNeil Janssen Scientific Affairs, and the American College of Obstetrics and Gynecology, and has done consultancy for Wyeth. All authors also declare no spouses, partners, or children with relationships with commercial entities that might have an interest in the submitted work; no non-financial interests that may be relevant to the submitted work.
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References