A report of a randomised controlled trial (RCT) should convey to the reader, in a transparent manner, why the study was undertaken, and how it was conducted and analysed. Inadequately reported randomisation, for example, has been associated with bias in estimating the effectiveness of interventions. To assess the strengths and limitations of an RCT, readers need and deserve to know the quality of its methods.

Despite several decades of educational efforts, RCTs are still not being reported adequately. For example, a review of 122 recently published RCTs that assessed the effectiveness of selective serotonin reuptake inhibitors as a first-line management strategy for depression found that only one paper described randomisation adequately. Inadequate reporting makes the interpretation of RCTs difficult, if not impossible. Moreover, inadequate reporting borders on unethical practice when biased results receive false credibility.

History of CONSORT

In the mid-1990s, two independent initiatives to improve the quality of reports of RCTs led to the publication of the CONSORT statement, which was developed by an international group of clinical trialists, statisticians, epidemiologists, and biomedical editors. CONSORT has been supported by a growing number of medical and health-care journals and editorial groups, including the International Committee of Medical Journal Editors (ICMJE, The Vancouver Group), the Council of Science Editors (CSE), and the World Association of Medical Editors (WAME). CONSORT is published in Dutch, English, French, German, Japanese, and Spanish. It can be accessed together with other information about the CONSORT group on the internet.

The CONSORT statement consists of a checklist and flow diagram for reporting an RCT. For convenience, the checklist and diagram together are called simply CONSORT. They are primarily intended for use in writing, reviewing, or assessing reports of simple two-group parallel RCTs.

Preliminary data indicate that the use of CONSORT does indeed help to improve the quality of reports of RCTs. In an assessment of 71 RCTs, published in three journals in 1994, allocation concealment was not clearly reported in 43 (61%) of the trials. 4 years later, after these three journals required that authors reporting an RCT use CONSORT, the proportion of papers in which allocation concealment was not clearly reported had dropped to 30 of 77 (39%, mean difference −22% [95% CI −38 to −6]).

The usefulness of CONSORT is increased by continuous monitoring of biomedical publications, which allows it to be modified dependent on the merits of maintaining or dropping current items, and including new items. For example, when Meinert observed that the flow diagram did not provide important information about the number of participants who entered each phase of an RCT (ie, enrolment, treatment allocation, follow-up, and data analysis), the diagram could be modified to accommodate the information. The checklist is similarly flexible.

This iterative process makes the CONSORT statement a continually evolving instrument. Although participants in the CONSORT group and their degree of involvement vary over time, members meet regularly to review the need to...
refine CONSORT. At the 1999 meeting, the participants decided to revise the original statement. This report reflects changes determined by consensus of the CONSORT group, partly in response to emerging evidence on the importance of various elements of RCTs.

**Revision of the CONSORT statement**

13 members of the CONSORT group met in May, 1999, with the main objective of revising the original CONSORT checklist and flow diagram, as needed. The group discussed the merits of including each item in the light of current evidence. As in developing the original CONSORT statement, our intention was to keep only those items deemed fundamental to reporting standards for an RCT. Some items not regarded as essential could well be highly desirable and should still be included in an RCT report even though they are not included in CONSORT. Such items include approval of an institutional ethics review board, sources of funding for the trial, and a trial registry number—eg, the International Standard Randomized Controlled Trial Number (ISRCTN) used to register the RCT at its inception. 17

Shortly after the meeting, a revised version of the checklist was circulated to the group for additional comments and feedback. Revisions to the flow diagram were similarly made. All these changes were discussed when CONSORT participants met in May, 2000, and the revised statement was finalised shortly afterwards.

The revised CONSORT statement includes a 22-item checklist (table) and a flow diagram (figure). Its main aim is to help authors improve the quality of reports of simple two-group parallel RCTs. However, the basic philosophy underlying the development of the statement can be applied to any design. In this respect, additional statements for other designs will be forthcoming from the group. CONSORT can also be used by peer reviewers and editors to identify reports with inadequate description of trials and those with potentially biased results. 1, 2

During the 1999 meeting, the group also discussed the benefits of developing an explanatory document to improve the use and dissemination of CONSORT. The document is patterned on reporting of statistical aspects of clinical research, 18 and was developed to help facilitate the recommendations of the ICMJE’s Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Three members of the CONSORT group, with assistance from members on some checklist items, drafted an explanation and elaboration document. That document 19 was circulated to the group for additions and revisions and was last revised after review at the latest CONSORT group meeting.

**Changes to CONSORT**

(1) In the revised checklist, a new column for “Paper section and topic” integrates information from the “Subheading” column that was contained in the original statement.

(2) The “Was it reported?” column has been integrated into a “reported on page number” column, as requested by some journals.

(3) Each item of the checklist is now numbered and the syntax and order have been revised to improve the flow of information.

(4) “Title” and “Abstract” are now combined in the first item.

(5) Although the content of the revised checklist is similar to the original, some items that were previously combined

---

### Checklist of items to include when reporting a randomised trial

<table>
<thead>
<tr>
<th>Item number</th>
<th>Item</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Title and abstract</td>
<td>How participants were allocated to interventions (eg, “random allocation”, “randomised”, or “randomly assigned”).</td>
</tr>
<tr>
<td>2</td>
<td>Introduction</td>
<td>Scientific background and explanation of rationale.</td>
</tr>
<tr>
<td>3</td>
<td>Methods</td>
<td>Eligibility criteria for participants and the settings and locations where the data were collected.</td>
</tr>
<tr>
<td>4</td>
<td>Interventions</td>
<td>Precise details of the interventions intended for each group and how and when they were actually administered.</td>
</tr>
<tr>
<td>5</td>
<td>Objectives</td>
<td>Specific objectives and hypotheses.</td>
</tr>
<tr>
<td>6</td>
<td>Outcomes</td>
<td>Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (eg, multiple observations, training of assessors, etc.).</td>
</tr>
<tr>
<td>7</td>
<td>Sample size</td>
<td>How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules.</td>
</tr>
<tr>
<td>8</td>
<td>Randomisation</td>
<td>Method used to generate the random allocation sequence, including details of any restriction (eg, blocking, stratification).</td>
</tr>
<tr>
<td>9</td>
<td>Sequence generation</td>
<td>Method used to implement the random allocation sequence (eg, numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned.</td>
</tr>
<tr>
<td>10</td>
<td>Allocation concealment</td>
<td>Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups.</td>
</tr>
<tr>
<td>11</td>
<td>Implementation</td>
<td>Whether or not participants, those administering the interventions, and those assessing the outcomes were aware of group assignment. If not, how the success of masking was assessed.</td>
</tr>
<tr>
<td>12</td>
<td>Blinding (masking)</td>
<td>Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses.</td>
</tr>
<tr>
<td>13</td>
<td>Statistical methods</td>
<td>Flow of participants through each stage (a diagram is strongly recommended). Specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analysed for the primary outcome. Describe protocol deviations from study as planned, together with reasons.</td>
</tr>
<tr>
<td>14</td>
<td>Results</td>
<td>Dates defining the periods of recruitment and follow-up.</td>
</tr>
<tr>
<td>15</td>
<td>Recruitment</td>
<td>Baseline demographic and clinical characteristics of each group.</td>
</tr>
<tr>
<td>16</td>
<td>Baseline data</td>
<td>Number of participants (denominator) in each group included in each analysis and whether the analysis was by “intention to treat”. State the results in absolute numbers when feasible (eg, 10/20, not 50%).</td>
</tr>
<tr>
<td>17</td>
<td>Numbers analysed</td>
<td>For each primary and secondary outcome, a summary of results for each group, and the estimated effect size and its precision (eg, 95% CI).</td>
</tr>
<tr>
<td>18</td>
<td>Outcomes and estimation</td>
<td>Number of participants (denominator) in each group included in each analysis and whether the analysis was by “intention to treat”. State the results in absolute numbers when feasible (eg, 10/20, not 50%).</td>
</tr>
<tr>
<td>19</td>
<td>Ancillary analyses</td>
<td>Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory.</td>
</tr>
<tr>
<td>20</td>
<td>Adverse events</td>
<td>All important adverse events or side-effects in each intervention group.</td>
</tr>
<tr>
<td>21</td>
<td>Discussion</td>
<td>Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision and the dangers associated with multiplicity of analyses and outcomes.</td>
</tr>
<tr>
<td>22</td>
<td>Interpretation</td>
<td>Generalisability (external validity) of the trial findings.</td>
</tr>
<tr>
<td>23</td>
<td>Generalisability</td>
<td>General interpretation of the results in the context of current evidence.</td>
</tr>
</tbody>
</table>
Discussion

Specifically developed to guide authors about how to improve the quality of reporting of simple two-group parallel RCTs, CONSORT encourages transparency with reporting of the methods and results so that reports of RCTs can be interpreted readily and accurately. However, CONSORT does not address other facets of reporting that also require attention, such as scientific content and readability of RCT reports. Some authors in their enthusiasm to use CONSORT have modified the checklist.24 We recommend against such modifications because they could be based on a different process from the one used by the CONSORT group.

The use of CONSORT seems to reduce, if not eliminate, inadequate reporting of RCTs.14,15 Potentially, the use of CONSORT should positively influence the manner in which RCTs are conducted. Granting agencies have noted this potential relation, and in at least one case25 have encouraged researchers to consider in their application how they have dealt with the CONSORT items.

The evidence-based approach used to develop CONSORT has also been used to develop standards for reporting meta-analyses of randomised trials,16 meta-analyses of observational studies,17 and diagnostic studies (Jeroen Lijmer, personal communication). Health economists have also started to develop reporting standards8 to help to improve the quality of their reports.25

The intent of all these initiatives is to improve the quality of reporting of biomedical research,19 and by doing so, to bring about more effective health care.

The revised CONSORT statement will replace the original one in the journals and groups that already support it. Journals that do not yet support CONSORT may do so by registering on the CONSORT website.13 To convey to authors the importance of improved quality in the reporting of RCTs, we encourage supporting journals to reference the revised CONSORT statement and the CONSORT internet address in their Instructions to Contributors. Since the journals publishing the revised CONSORT statement have waived copyright protection, CONSORT is now widely accessible to the biomedical community. The CONSORT checklist and flow diagram can also be accessed at the CONSORT website.

A lack of clarification of the meaning and rationale for each checklist item in the original CONSORT statement has been remedied with the development of the CONSORT explanation and elaboration document13 which can also be found on the CONSORT website. This document reports the evidence on which the checklist items are based, including the references, which had annotated the checklist items in the previous version. We also
encourage journals to include reference to this document in their Instructions to Contributors.

Emphasising the evolving nature of CONSORT, the CONSORT group invites readers to comment on the updated checklist and flow diagram through the CONSORT website. Comments and suggestions will be collated and considered at the next meeting of the group in 2001.

Contributors

David Moher, Ken Schulz, and Doug Altman participated in regular conference calls, identified participants, participated in the CONSORT meetings, and drafted the paper. David Moher and Leah Lepage provided the CONSORT meetings, identified and secured funding, invited the participants, and planned the meeting agenda. The members of the CONSORT group listed below attended the CONSORT meetings and provided input towards the revised checklist, flow diagram, and text.

The CONSORT group

Frank Davidoff (Annals of Internal Medicine, Philadelphia, PA, USA); Susan Eastwood (University of California at San Francisco, CA, USA); Matthias Egger (Department of Social Medicine, University of Bristol, UK); Diana Elbourne (London School of Hygiene and Tropical Medicine, London, UK); Peter Gotzsche (Nordic Cochrane Centre, Copenhagen, Denmark); Sylvan B Green (School of Medicine, Case Western Reserve University, Cleveland, OH, USA); Lenie Eggerman (Merck & Co, Whitehouse Station, NJ, USA); Barbara S Hawkins (Wilmer Ophthalmological Institute, Johns Hopkins University, Baltimore, MD, USA); Richard Horton (The Lancet, London, UK); Wayne B Jonas (Uniformed Services University of the Health Sciences, Bethesda, MD); Terry Klassen (Department of Pediatrics, University of Alberta, Edmonton, Alberta, Canada); Leah Lepage (Thomas C Chalmers Centre for Systematic Reviews, Ottawa, Ontario, Canada); Thomas Lang (Tom Lang Communications, Lakewood, OH, USA); Jeroen Lijmer (Department of Clinical Epidemiology, University of Amsterdam, Netherlands); Rick Malone (TAP Pharmaceuticals, Lake Forest, IL, USA); Curtis L Meinert (Johns Hopkins University, Baltimore, MD, USA); Mary Mosley (Life Science Publishing, Tokyo, Japan); Stuart Pocock (London School of Hygiene and Tropical Medicine, London); Drummond Rennie (Journal of the American Medical Association, Chicago, IL); David S Riley (University of New Mexico Medical School, Santa Fe, NM, USA); Roberta W Scherer (Epidemiology & Preventive Medicine, University of Maryland School of Medicine, Baltimore, MD); Ida Sim (University of California at San Francisco, CA); Donna Stroup (Epidemiology Program Office, Centers for Disease Control and Prevention, Atlanta, GA, USA).

Acknowledgments

The effort to improve the reporting of randomised trials, from its beginnings with the Standards of Reporting Trials (SORT) group to the current activities of the Consolidated Standards of Reporting Trials (CONSORT) group, has involved many people around the globe. We thank Leah Lepage for keeping everybody all lined up and moving in the same direction. Financial support to convene meetings of the CONSORT group was provided in part by Abbott Laboratories, American College of Physicians, GlaxoWellcome, The Lancet, Merck, the Canadian Institutes for Health Research, National Library of Medicine, and TAP Pharmaceuticals.

References

25. O'Toole LB. MRC uses checklist similar to CONSORT's. JAMA 1997; 314: 1127.