Consolidated standards of Reporting Trial revised

The CONSORT Statement II

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Gruppo Italiano per la Medicina Basata sulle Evidenze
“Randomized controlled trials are the standard of excellence for scientific studies of effects of treatment.”

Fletcher & Fletcher & Wagner, 1996

“RCT is a very beautiful technique, of wide applicability, but as with everything else there are snags. When humans have to make observations there is always the possibility of bias.”

Al. Cochrane
What is “quality” of an RCT?

- The **clinical relevance** of the research question.

- The **internal validity** of the trial (the degree to which the trial design, conduct, analysis, and presentation have minimised or avoided biased comparisons of the interventions under evaluation).

- The **external validity** (the precision and extent to which it is possible to generalise the results of the trial to other settings).

- The **appropriateness** of data analysis and presentation.

- The **ethical implications** of the intervention evaluated.  
  
  *Jadad, A. 2000*
Reporting RCT: Key quality elements usefulness for interpretation of results

1) *Is the topic interesting to you?*
   Title, introduction objective, (but the information in the title and the abstract could give you a misleading message)

2) *Are the results likely to be unbiased?*
   Research design, participants, interventions, main outcome measures, results, sampling frame, approach by the investigators, criteria used to include prospective participants or to exclude them, interventions, randomisation and blinding method and implementation, measure of outcomes, methods of analysis

3) *Would you be able to use the results?*
   Clinical setting

4) *Are the results important enough for you to remember?*
How well RCT are reported?

Statement about sample size: 11.1%
Use of confidence intervals: 13.3%


Information about type of randomization: 40%


How the randomization sequence was generated: 32%
How intervention assignment was concealed: 22.8%

Standard of Reporting Trials
SORT
(JAMA 1994)

Asilomar Working Group
on Recommenation for
Reporting of
Clinical Trials in the
Biomedical Literature
(Ann Intern Med 1996)

CONSORT I
Clinical Trialist
methodologists
epidemiologists
statisticians
editors
Beyond CONSORT: Need for Improved Reporting Standards for Clinical Trials

Curtis L. Meinert, PhD

JAMA, May 13, 1998—Vol 279, No. 18
The Revised CONSORT Statement for Reporting Randomized Trials: Explanation and Elaboration

Douglas G. Altman, DSc; Kenneth F. Schulz, PhD; David Moher, MSc; Matthias Egger, MD; Frank Davidoff, MD; Diana Elbourne, PhD; Peter C. Gøtzsche, MD; and Thomas Lang, MA, for the CONSORT Group

17 April 2001 | Annals of Internal Medicine | Volume 134 • Number 8 | 663
CONSORT II flow-chart: showing all numbers to prevent bias
The CONSORT II check-list

Items to include when Reporting a randomized trial

• Title and abstract

• Introduction: background

• Methods: participants, intervention, objectives, outcomes, sample size

• Randomization: sequence generation, allocation concealment, implementation

• Blinding

• Statistical methods

• Results: participant flow, recruitment, baseline data, number analyzed, outcome and estimation, ancillary analyses, adverse events

• Discussion: interpretation, generalizability, overall evidence
The CONSORT II glossary

GLOSSARY

Adjusted analysis: Usually refers to attempts to control (adjust) for baseline imbalances between groups in important patient characteristics. Sometimes used to refer to adjustments of $P$ value to take account of multiple testing. See Multiple comparisons.

Adverse event: An unwanted effect detected in participants in a trial. The term is used regardless of whether the effect can be attributed to the intervention under evaluation. See also Side effect.

Allocation concealment: A technique used to prevent selection bias by concealing the allocation sequence from those assigning participants to intervention groups, until the moment of assignment. Allocation concealment prevents researchers from (unconsciously or otherwise) influencing which participants are assigned to a given intervention group.

Allocation ratio: The ratio of intended numbers of participants in each of the comparison groups. For two-group trials, the allocation ratio is usually 1:1, but unequal allocation (such as 1:2) is sometimes used.
The CONSORT II web site

www.consort-statement.org
Use of the CONSORT Statement and Quality of Reports of Randomized Trials
A Comparative Before-and-After Evaluation

David Moher, MSc
Alison Jones, BA
Leah Lepage, PhD
for the CONSORT Group

**Context**  The Consolidated Standards for Reporting of Trials (CONSORT) statement was developed to help improve the quality of reports of randomized controlled trials (RCTs). To date, a paucity of data exists regarding whether it has achieved this goal.

**Objective**  To determine whether use of the CONSORT statement is associated with improvement in the quality of reports of RCTs.

1992  JAMA, April 18, 2001—Vol 285, No. 15
Jadad quality scale

1. Was the study described as randomised?
2. Was the study described as double blind?
3. Was there a description of withdrawals and drop outs?

Give a score of 1 point for each "yes" or 0 points for each "no"

Give 1 additional point each

Deduct 1 point each

If randomisation/blinding appropriate

If randomisation/blinding inappropriate

Scoring range: 0–5
Poor quality <3
CONSORT Checklist of 40 Criteria Included in Reports of Randomized Trials for Articles Published in *BMJ*, *JAMA*, *The Lancet*, and *NEJM* during the First Half of 1994 and 1998

<table>
<thead>
<tr>
<th>Total (n = 40)</th>
<th><em>BMJ</em></th>
<th><em>JAMA</em></th>
<th><em>Lancet</em></th>
<th>Total Adopters</th>
<th><em>NEJM</em> (Comparator)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1994, Mean (SD)</td>
<td>21.1 (4.2)</td>
<td>26.0 (4.6)</td>
<td>21.8 (4.8)</td>
<td>23.4 (5.1)</td>
<td>22.0 (3.0)</td>
</tr>
<tr>
<td>1998, Change (95% CI)</td>
<td>6.4 (2.9 to 9.9)‡</td>
<td>1.6 (–0.8 to 4.0)</td>
<td>4.9 (2.5 to 7.3)‡</td>
<td>3.7 (2.1 to 5.3)‡</td>
<td>0.8 (–1.1 to 2.7)</td>
</tr>
</tbody>
</table>

*CONSORT indicates Consolidated Standards for Reporting of Trials; CI, confidence interval.
†P<.05 (2-sided).
‡P<.001 (2-sided).
Quality of Reports of Randomized Trials, Using an Assessment Tool, for Articles Published in *BMJ, JAMA, The Lancet,* and *NEJM* during the First Half of 1994 and 1998

<table>
<thead>
<tr>
<th>Journal</th>
<th>Total No. of Items</th>
<th>1994, Mean (SD)</th>
<th>1998, Mean (SD)</th>
<th>1994, Change (95% CI)</th>
<th>1998, Change (95% CI)</th>
<th>1994, % Dropout/Withdrawals</th>
<th>1998, % Dropout/Withdrawals</th>
<th>Total</th>
<th>1994, Mean (SD)</th>
<th>1998, Mean (SD)</th>
<th>1994, Change (95% CI)</th>
<th>1998, Change (95% CI)</th>
<th>1994, % Unclear Allocation Concealment</th>
<th>1998, % Unclear Allocation Concealment</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMJ</td>
<td>14 20</td>
<td>1.1 (0.4)</td>
<td>0.4 (0.04 to 0.8)†</td>
<td>0.2 (0.6) 0.1 (−0.4 to 0.5)</td>
<td>71 (−6 to −40 to 28) 2.1 (0.9)</td>
<td>0.4 (−0.3 to 1.2)</td>
<td>79 (−29 to −62 to 4)</td>
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<tr>
<td>JAMA</td>
<td>29 20</td>
<td>1.3 (0.6)</td>
<td>0.1 (−0.3 to 0.4)</td>
<td>0.9 (0.8) 0.2 (−0.3 to 0.8)</td>
<td>76 (4 to −21 to 29) 3.0 (1.0)</td>
<td>0.4 (−0.3 to 1.0)</td>
<td>59 (−14 to −43 to 16)</td>
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<td>Lancet</td>
<td>28 37</td>
<td>1.2 (0.4)</td>
<td>0.4 (0.1 to 0.6)†</td>
<td>0.6 (0.8) 0.3 (−0.2 to 0.7)</td>
<td>96 (1 to −8 to 10) 2.8 (0.9)</td>
<td>0.7 (0.1 to 1.2)†</td>
<td>54 (−24 to −48 to 1)</td>
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<tr>
<td>Total Adopters</td>
<td>71 77</td>
<td>1.2 (0.5)</td>
<td>0.3 (0.1 to 0.4)†</td>
<td>0.6 (0.8) 0.2 (−0.1 to 0.4)</td>
<td>83 (1 to −11 to 13) 2.7 (1.0)</td>
<td>0.4 (0.1 to 0.9)§</td>
<td>61 (−22 to −38 to −6)</td>
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<tr>
<td>NEJM comparator</td>
<td>26 37</td>
<td>1.4 (0.5)</td>
<td>0.02 (−0.2 to 0.3)</td>
<td>0.8 (1.0) 0.3 (−0.4 to 0.5)</td>
<td>92 (−6 to −21 to 10) 3.1 (1.0)</td>
<td>−0.01 (−0.6 to 0.5)</td>
<td>69 (−8 to −33 to 17)</td>
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*CI indicates confidence interval.
†P < .05 (2-sided).
‡P = .01 (2-sided).
§P = .02 (2-sided).
||P = .008 (2-sided).
What is “quality” of an RCT?

- The **clinical relevance** of the research question.
- The **internal validity** of the trial (the degree to which the trial design, conduct, analysis, and presentation have minimised or avoided biased comparisons of the interventions under evaluation).
- The **external validity** (the precision and extent to which it is possible to generalise the results of the trial to other settings).
- The **appropriateness** of data analysis and presentation.
- The **ethical implications** of the intervention evaluated.
The CONSORT Statement: original objectives & hopeful results - 1

Objective

- To improve the standard of written reports of RCTs (for writers)

Results - 1

- To lead an improvement in the quality of RCTs as result of authors being aware of the requirements for submission of trial reports
The CONSORT Statement: original objectives & hopeful results - 2

Results - 2

• To facilitate critical appraisal and interpretation of RCTs by providing guidance:
  • To **author** about how to improve the reporting of their trials
  • To **peer-reviews and editors** to identify reports that are difficult to interpret and those with potentially biased results
  • To **clinician** to judge whether the results of a trial are credible
  • To **reviewer** to decide how much each trial should influence the overall analysis of all evidence available on a particular topic
  • to **administrator** to deciding whether to purchase a service or a new intervention
<table>
<thead>
<tr>
<th>JOURNAL</th>
<th>ENDORSING HOW</th>
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</thead>
<tbody>
<tr>
<td>Annals of Emergency Medicine</td>
<td>instructions to authors completed checklist required</td>
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<tr>
<td>Annals of Internal Medicine</td>
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<td>Archives of Dermatology</td>
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<td>Scandinavian Journal of Gastroenterology</td>
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</table>
“I numeri possono essere torturati fino a che non confessano”

Anonimo

“...Ma una bugia ne rende necessarie molte altre”

Anonimo