


 L'Integrità della Ricerca Biomedica  
 nell'era dell'Evidence-based Health Care  
**GIMBE**  
Associazione Italiana per la Medicina Basata sulle Evidenze  
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**Istituti Ortopedici Rizzoli**

**Consolidated standards  
 of Reporting Trial revised  
 The CONSORT Statement II**

**Massimo Annicchiarico**  
*Azienda USL Bologna Nord*

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*" 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 %  
*Pocock SJ, N Engl J Med. 1987;317:426-432.*

Information about type of randomization: 40%  
*Altman DG, Lancet. 1990;335:149-153.*

How the randomization sequence was generated: 32%  
 How intervention assignment was concealed. 22,8%  
*Schulz KF, JAMA. 1994;272:125-128.*

**Standard of Reporting Trials  
 SORT  
 (JAMA 1994)**

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

**JAMA**  
Journal of the American Medical Association  
 Special Commemorative edition - August 7th, 1996.  
**Improving the Quality of Reporting of  
 Randomized Controlled Trials**  
**The CONSORT Statement**  
Leslie H. Brant, PhD; Michael Clarke, PhD; Nancy K. Assmann, MD; Richard J. Glazer, MD; David L. Johnson, MD; Stephen O'Brien, PhD; Ron Packer, MD; Emmanuel Rattin, MD; Kenneth P. Schulz, PhD; David Sackett, MD; Charles F. Spangola, PhD

**CONSORT I  
 Clinical Trialist  
 methodologists  
 epidemiologists  
 statisticians  
 editors**

Controversies

Beyond CONSORT: Need for Improved Reporting Standards for Clinical Trials

Curtis L. Mulrow, MD

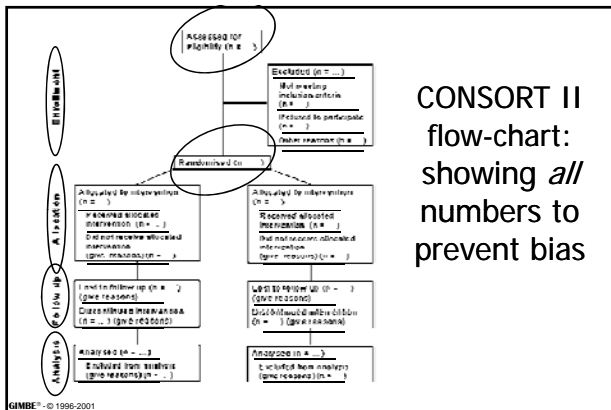
JAMA, May 13, 1996—Vol 279, No. 10

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Exploration and Expansion  
The Revised CONSORT Statement for Reporting Randomized Trials:

17 April 2001 | Annals of Internal Medicine | Volume 134 • Number 8 | 663

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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

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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 values 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.

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The CONSORT II web site

www.consort-statement.org

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## 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-reviewers 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

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## Which Journals completely endorse *CONSORT* and how ?

<i>JOURNAL</i>	<i>ENDORISING HOW</i>	
Annals of Emergency Medicine	instructions to authors	completed checklist required
Annals of Internal Medicine	instructions to authors	completed checklist required
Archives of Dermatology	instructions to authors	completed checklist required
Archives of Family Medicine	instructions to authors	completed checklist required
British Medical Journal	instructions to authors	completed checklist required
Journal of the American Medical Association		completed checklist required
Obstetrics and Gynecology	instructions to authors	completed checklist required
Scandinavian Journal of Gastroenterology	instructions to authors	completed checklist required

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*"I numeri possono essere  
torturati fino a che non  
confessano"*

Anonimo

*" ...Ma una bugia ne rende  
necessarie molte altre"*

Anonimo

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