"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%
Beyond CONSORT: Need for Improved Reporting Standards for Clinical Trials

**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**

**Assignment:** Usually refers to attempts to control confounding by matching those in treatment groups to important patient characteristics. Sometimes used as a synonym of “randomization,” particularly in multiple regression, see also “allocation concealment.”

**Allocation concealment:** A technique used to prevent selection bias by ensuring that chance assignments from those assigning participants to intervention groups, until the moment of assignment, remain concealed from investigators (or persons otherwise involved) influencing which participants are assigned to a given intervention group.

**Randomization:** The use of a randomization scheme to assign participants to intervention groups. For example, if intervention groups are matched 1:1, the allocation may be random (such as flipping a coin) in a manner similar to flipping a coin.
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

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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

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-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?**

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<tr>
<th>JOURNAL</th>
<th>ENDORSING HOW</th>
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<tr>
<td>Annals of Emergency Medicine</td>
<td>instructions to authors</td>
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<tr>
<td>Annals of Internal Medicine</td>
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<td>Scandinavian Journal of Gastroenterology</td>
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“I numeri possono essere torturati fino a che non confessano”

Anonimo

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

Anonimo