



## ORIGINAL ARTICLE

# Influence of trial registration on reporting quality of randomized trials: Study from highest ranked journals

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**Abstract**

**Objective:** To evaluate the reporting quality of key methodological items of randomized control trials (RCTs) in 55 of the highest ranked journals.

**Study Design and Setting:** A list of the highest top ranked journals was identified, and a search for detecting RCTs in those journals was made. Two hundred sixty four journals were screened and 55 of them were identified having at least one RCT. Three RCTs were randomly selected a priori from each journal; 148 RCTs were finally included. RCTs were assessed by two reviewers using the Consolidated Standards of Reporting Trials (CONSORT) statement.

**Results:** Only 11 (8%) RCTs had all items adequately reported. In addition, 36% of RCTs reported that the study was registered in any trial registry. We found a significant difference in the quality of reporting for baseline characteristics, recruitment, participant's flow, and randomization implementation between those studies having reported the registration of their RCT in a trial registry and those that have not. Adherence to key methodological items of the CONSORT statement was as follows: sample size determination (60%), sequence generation (49%), allocation concealment (40%), and blinding (25%).

**Conclusions:** Reporting of varied CONSORT items remains suboptimal. Registration in a trial registry was associated with improved reporting. Further efforts to enhance RCT registration could contribute to this improvement. © 2010 Elsevier Inc. All rights reserved.

**Keywords:** Randomized controlled trials; Clinical trials; Editorial policies; Quality control; Bias; Methods

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**1. Introduction**

The Consolidated Standards of Reporting Trials (CONSORT) statement was first developed in 1996 and updated in 2001 [1,2] with the aim of improving the reporting

of randomized controlled trial (RCT) as well as enabling readers to understand its conduct and to estimate the validity of its results [3]. Extensions of the CONSORT statement have been developed to provide guidance for RCTs with specific designs, data, and interventions. Editorial groups, such as the Council of Science Editors, the International Committee of Medical Journal Editors (ICMJE), and the World Association of Medical Editors (WAME) as well as more than 150 medical, clinical, and psychological journals have endorsed CONSORT. It requires trial lists and journal articles to follow a checklist of 22 items and a four-stage flow diagram along with a brief descriptive text. The checklist items focus on reporting how the trial was designed, analyzed, and interpreted and the flow

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**What is new?**

Registration in an International Clinical Trial Registry was associated with improved reporting. Further efforts to enhance randomized controlled trial (RCT) registration could contribute to this improvement. Reporting of varied Consolidated Standards of Reporting Trials (CONSORT) items remains suboptimal, and there is still significant need for improvement in high ranked journals. As suggested by the International Committee of Medical Journal Editors (ICMJE), all journals publishing RCTs should require prospective trial registration identification number to improve the quality of reporting.

diagram displays the progress of all participants through the trial [4].

Since the publication of CONSORT, a number of studies have evaluated its effectiveness for improving the quality of reporting. A systematic review to determine whether the adoption of the CONSORT checklist was associated with the improvement in the quality of RCTs found that CONSORT adopters had reported significantly better the method of sequence generation (risk ratio [RR]: 1.67; 95% confidence interval [CI]: 1.19–2.33), allocation concealment (RR: 1.66; 95% CI: 1.37–2.00), and overall number of CONSORT items than nonadopters (standardized mean difference [SMD]: 0.83; 95% CI: 0.46–1.19) [3]. When evaluating CONSORT-adopting journals before and after the publication of CONSORT, description of the method of sequence generation (RR: 2.78; 95% CI: 1.78–4.33), participant flow (RR: 8.06; 95% CI: 4.10–15.83), and total CONSORT items (SMD: 3.67 items; 95% CI: 2.09–5.25) were improved after adoption of CONSORT by the journal.

Varied publications reported the assessment of the quality of RCT by conducting cross-sectional or observational studies to examine the extent to which they adhere to the CONSORT statement [5–10]. Most studies found that although reporting some CONSORT recommendations have improved over time, the reporting of several essential recommendations remains suboptimal and in need for significant improvement [5–12].

The impact factor (IF) is a measure of the citations of the science journals; it is used as an alternative to estimate the importance of a journal [13,14]. Although, it could be assumed that the highest ranked journal may have better quality reporting methods, but at the best of our knowledge, there are no studies evaluating the quality of reporting in this specific journal subset.

The number of registries and registered clinical trials has been increasing dramatically since 2004, after the requirement for registration at inception in a public register was introduced by several medical journals. Published protocols are a particularly valuable source of information when they

are fully available. However, few protocols are currently publicly available and information is not standardized and is often found in the form of long essay documents, which hamper the search for the information needed. Currently, the main source of essential protocol information can be found in trial registries, which aim at providing the essential information as defined by the World Health Organization (WHO) standards. There is general agreement about the minimum protocol information that should be registered for a trial, as defined by the 20-item of the WHO Registration Data Set [15–18].

Our study aimed to evaluate the reporting quality of key methodological items of RCTs of the 55 highest ranked journals. We also aim to compare the reporting quality between journals that have reported registration in an International Clinical Trials Registry and those that have not.

**2. Methodology***2.1. Study design*

We conducted a cross-sectional study to evaluate the reporting quality of key methodological items of RCTs among the highest ranked journals.

*2.2. Sample**2.2.1. Eligibility criteria*

Inclusion criteria included: (1) the report was published between January 1 and December 31, 2007, (2) the report was published as an original article, (3) the study groups were reported to have been randomly assigned (the report had to explicitly use the word “random” or variations thereof, otherwise it was excluded.).

*2.2.2. Selection of RCT reports*

The Thomson Scientific’s Journal Citation Reports was used to identify a list of the highest ranked journals in 2006. IFs are calculated each year by Thomson Scientific for those journals that it indexes, and each year, covered publication takes place in the summer of the following year [13,14]. A structured search for identifying RCTs (Appendix A) in those journals was made in PUBMED from January 1st, 2007 to December 31st, 2007. The journals not indexed in PUBMED were also searched through their own websites and SCIRUS ([www.scirus.com](http://www.scirus.com)). Titles and abstracts of 12,363 references were identified and screened from 264 highest ranked journals. Fifty-five journals were identified having at least one published RCT in 2007 (Appendix B). Three RCTs were randomly selected a priori from each journal when possible (taken into account that not all journals published at least three RCTs during the period studied).