Original Article

Quality of Reports on Randomized Controlled Trials Published in Iranian Journals: Application of the New Version of Consolidated Standards of Reporting Trials (CONSORT)

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Abstract

Background: The Consolidated Standards for Reporting of Trials (CONSORT) statement is a device to standardize reporting and improve the quality of controlled trials. The aim of this study is to determine the quality of controlled clinical trial reports by national peer-reviewed journals in Iran.

Methods: In a cross-sectional study, we evaluated clinical trial reports by national peer-reviewed Iranian journals between 2008 and 2010 by CONSORT2010. The sample was selected from Iran Medex. The proportion of adherence to each item of the CONSORT checklist was assessed for each clinical trial. The reliability of evaluation by reviewers was calculated by Pearson correlation coefficient, and was determined to be 0.73 – 0.89, with a significance level of $P < 0.01$ between reviewers.

Results: A total of 509 articles published in 80 peer-reviewed national journals were evaluated. The average adherence of evaluated randomized controlled trials (RCTs) to the 37 items of the CONSORT statement was 43.8%. The mean CONSORT score significantly differed across each year of publication. None of the articles mentioned the location where the full trial protocol could be accessed.

Conclusion: The quality of reporting RCTs published in national peer-reviewed journals needs significant improvement as the majority did not adhere to CONSORT guidelines. It is necessary for the editors of Iranian journals to consider CONSORT criteria for evaluation of all future RCTs.

Keywords: Clinical trials, consort statement, controlled trials, peer-reviewed journals

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Introduction

Randomized controlled trials (RCTs) are known as the gold standard for evaluating the efficacy and effectiveness of health care interventions.[1,2] However, it has been shown that various biases can arise during the design, performance, and reporting stages of these studies.[2,3] Evidence indicates that the quality of publishing RCTs in medical journals is less than optimal.[4,5]

In a review by Chan et al., 519 RCTs indexed in PubMed and published in December 2000 were assessed.[6] They showed that 82% of authors did not report the method of allocation concealment.

To address this defect and standardize reporting of RCTs, the Consolidated Standards for Reporting of Trials (CONSORT) criteria were issued in 1996,[7] then revised twice, in 2001[6] and 2010.[3] The objective of CONSORT is to provide a guideline for authors to improve the reporting of their trials.[3]

A number of controlled clinical trials have been conducted in Iran. Recent reports indicate improving the quantity of reporting RCTs.[8] However the quality of these studies needs additional attention. One study which had assessed the quality of published RCTs in national journals in 2003 indicated that only 6.2% of authors mentioned a method for sample size calculation.[9]

The aim of this study was to evaluate the quality of reporting RCTs published in peer-reviewed Iranian journals from 2008 to 2010, by using a checklist based on the CONSORT statement.

Materials and Methods

Journal and randomized controlled trial (RCT) selection

All national peer-reviewed journals published from 2008 to 2010 were evaluated using the IranMedex database. IranMedex covers about 69899 articles across 225 national journals. We used the search term, "*randomized controlled trial*". Then, we conducted an advanced search for articles with the following criteria: "RCT" mentioned in the abstract or title, availability of the complete text, published between 2008 to 2010, and published as an original paper. This study was supported by Technology Affairs of Tehran University of Medical Sciences.

Assessing randomized controlled trials (RCTs)

We evaluated all articles using the CONSORT 2010 checklist.[3] This checklist has 25 essential elements and subdivisions that consist of 37 items in total. Elements of CONSORT 2010 evaluate internal and external validity of all sections of RCTs, including methods, results, and discussion. The revised CONSORT statement published in 2010 has modified the original checklist and flow diagram. Each item of CONSORT has a dichotomous scale (described = 1, not described = 0). Therefore, the maximum score

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for an article using the CONSORT 2010 criteria is 37.

Four items (3b, 6b, 7b, and 14b) were not applicable for evaluated RCTs in this study. Therefore, to calculate the total score of the checklist we agreed to assign a point value of 1 for each of these items.

Five independent reviewers experienced and knowledgeable in clinical research evaluated the articles. To standardize evaluation, all reviewers participated in a panel to describe the checklist and discuss items. A checklist was completed by the reviewers and disagreements in item scores were discussed. After reaching a consensus about all items, evaluation of the articles was begun. We randomly selected 66 articles (13%) from three reviewers (22 articles per reviewer) for assessment of reliability and consistency of the evaluations. After finishing the first evaluation, these 66 articles were assessed again.

Statistical analysis

Data was analyzed using the SPSS software for Windows, version 18.0 (SPSS Inc., Chicago, IL). Descriptive statistics were performed on the number and proportion of articles by year of publication and journals. One way analysis of variance was used to compare the difference between years of publication and mean scores. We used Scheffe as a post hoc test. Pearson correlation coefficient was calculated to assess correlation between total scores across reviewers as an interrater reliability index. All statistical tests were two-tailed, with a significance level of 0.05.

Results

Therefore, 509 RCTs from 80 journals fulfilled our inclusion criteria and were entered in the final analysis (Figure 1). Pearson correlation coefficients for three pairs of evaluators were from 0.73 – 0.89 at a significance level of $P < 0.01$ between the evaluators. Mean score of the CONSORT items was 19.04 ± 2.95 for all 509 evaluated RCTs. The CONSORT mean score differed significantly across years of publication, from 2008 (18.5 ± 2.7) to 2010 (19.9 ± 3.0; $P = 0.001$).

Table 1 illustrates the adherence of 509 RCTs to the 37 items of the CONSORT. The most common (99%) item was "Structured summary of trial design, methods, results, and conclusions". Just 6 (1.2%) articles completely defined pre-specified primary and secondary outcome measures.

None of the articles mentioned where the full trial protocol could be accessed. The average adherence of evaluated RCTs to the 37 methodological items of the CONSORT statement was 43.8%.

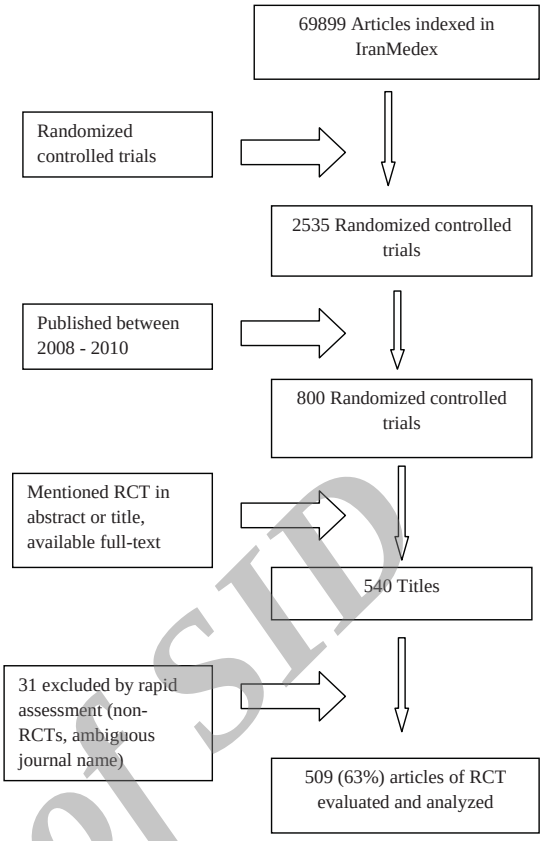

Figure 1. Flow chart of articles selected for analysis.

Discussion

In this study we have observed that the majority of RCTs reported in national journals did not adhere to CONSORT guidelines. Writing a proper introduction with mention of the advantages and disadvantages of previous studies is the first step in reporting a clinical trial. In our study, 86.6% of the articles have reported the scientific background and explained the study's rationale. Reporting objectives and hypotheses were noted at a rate of 73.1% for evaluated RCTs. Therefore, adherence to these two CONSORT items with regards to the introduction was acceptable.

Completely defined pre-specified primary and secondary outcome measures were reported by just 1.2% of the articles. Type of randomization and mechanism used to implement the randomization allocation sequence were reported by approximately 4% to 8% of the articles. "Who generated the random allocation sequence" is an important item; however this was only mentioned in 4.9% of the articles. A proper type of randomization can provide for acceptable comparability between groups. In one study conducted in Iran, just 1.3% of articles had mentioned the type of randomization.[9] Therefore, it seems, the quality of RCTs from this aspect has improved. In the current study, about 30% of evaluated articles have reported the method of sample size calculation. In a study by Ayatolahi et al., 6.2% reported the method of sample size calculation,[10] which indicated an increase in quality of RCTs in this regard.

The positive aspects of published articles in national journals included: description of trial design in "Methods" (75.4%), reporting eligibility criteria for participants (93.3%), reporting settings and locations where data were collected (84.1%), definition of the interventions for each group with sufficient details to allow replication (98.8%), and reporting statistical methods used to compare groups for primary and secondary outcomes (96.3%).

Just 8.4% of evaluated articles presented both absolute and relative effect sizes for binary outcomes. One possible explanation could be the lack of knowledge that authors may have about biostatistics and not having a biostatistician or epidemiologist on the team that prepared the study.

Mentions about trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses were important items in each of the trials. A total of 139 (27.3%) articles had adhered to this item. Reporting limitation of the studies can assist readers in having a better interpretation of the results.

Table 1. Adherence of evaluated randomized controlled trials (RCTs) to CONSORT 2010.

Item	Checklist item	Yes n (%)	No n (%)
1a	Identification as a randomized trial in the title	35 (6.9)	474 (93.1)
1b	Structured summary of trial design, methods, results, and conclusions	504 (99)	5 (1.0)
2a	Scientific background and explanation of rationale	441 (86.6)	68 (13.4)
2b	Specific objectives or hypotheses	372 (73.1)	137 (26.9)
3a	Description of trial design (such as parallel, factorial) including allocation ratio	384 (75.4)	125 (24.6)
3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons *	----	------
4a	Eligibility criteria for participants	475 (93.3)	34 (6.7)
4b	Settings and locations where the data were collected	428 (84.1)	81 (15.9)
5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	503 (98.8)	6 (1.2)
6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	6 (1.2)	503 (98.8)
6b	Any changes to trial outcomes after the trial commenced, with reasons *	----	----
7a	How sample size was determined	152 (29.9)	357 (70.1)
7b	When applicable, explanation of any interim analyses and stopping guidelines *	----	-----
8a	Method used to generate the random allocation sequence	194 (38.1)	315 (61.9)
8b	Type of randomization; details of any restriction (such as blocking and block size)	40 (7.9)	469 (92.1)
9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	19 (3.7)	490 (96.3)
10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	25 (4.9)	484 (95.1)
11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	206 (40.5)	303 (59.5)
11b	If relevant, description of the similarity of interventions	229 (45.0)	280 (55.0)
12a	Statistical methods used to compare groups for primary and secondary outcomes	490 (96.3)	19 (3.7)
12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	117 (22.9)	392 (77.0)
13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	177 (34.8)	332 (65.2)
13b	For each group, losses and exclusions after randomization, together with reasons	128 (25.1)	381 (74.9)
14a	Dates defining the periods of recruitment and follow-up	133 (26.1)	376 (73.9)
14b	Why the trial ended or was stopped *	----	-----
15	A table showing baseline demographic and clinical characteristics for each group	256 (50.3)	253 (49.7)
16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	170 (33.4)	339 (66.6)
17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	509 (98.2)	9 (1.8)
17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	43 (8.4)	466 (91.6)
18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	453 (89.0)	56 (11.0)
19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	114 (22.4)	395 (77.6)
20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	139 (27.3)	370 (72.7)
21	Generalizability (external validity, applicability) of the trial findings	361 (70.9)	148 (29.1)
22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	478 (93.9)	31 (6.1)
23	Registration number and name of trial registry	63 (12.4)	446 (87.6)
24	Where the full trial protocol can be accessed, if available	0 (0)	509 (100)
25	Sources of funding and other support (such as supply of drugs), role of funders	129 (25.3)	380 (74.7)

* Not applicable

Registration of trials is a necessary item for reporting RCTs in most journals. In the current study, 12.4% of articles had reported the name of the trial registry. Sources of funding and other support for trials were reported by 25.3%. In a study by Uetani et al., only 20% of articles had mentioned the source of funding.[10]

A limitation of our study could be the application of a score of one to some of the not applicable items of the checklist, which could have inflated the mean score. Another limitation was the use of only one search term, which caused us to miss some relevant articles.

A merit of the current study was the wide range of articles and large sample of national RCTs. Wide coverage by IranMedex on national peer-reviewed journals provided this accessibility.

In conclusion, we have found that the quality of reporting RCTs published in national peer-reviewed journal is in need of improvement as the majority of RCTs did not adhere to CONSORT guidelines.

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References

1. Peto R, Collins R, Gray R. Large-scale randomized evidence: Large sample trials and overviews of trials. *J Clin Epidemiol*.1995; **48:** 23 – 40.
2. Jüni P, Altman DG, Egger M. Systematic reviews in health care: assessing the quality of controlled clinical trials. *BMJ*. 2001; **323:** 42 – 46.
3. Moher D, Hopewell S, Schulz KF, Montori V, Gøtzsche PC, Devereaux PJ, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomized trials. *J of Ciln Epidemiol*. 2010; doi: 10.1016/j.jclinepi.2010.03.004.
4. Schulz KF, Chalmers I, Grimes DA, Altman DG. Assessing the quality of randomization from reports of controlled trials published in obstetrics and gynecologic journals. *JAMA*. 1994; **272:** 125 – 128.
5. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendation for improving the quality of reports of parallel group randomized trials. *Lancet*. 2001; **357:** 1191 – 1194.
6. Chan AW, Altman DG. Epidemiology and reporting of randomized trials published in PubMed journals. *Lancet*. 2005; **365:** 1159 – 1162.
7. Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, et al. Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA*. 1996; **276:** 637 – 639.
8. Iran is the fastest growing scientific power. Available from: URL: http://www.oochoo.com/2010/02/iran-is-the-fastest-growing-scientific-power (Accessed Date: 10/13/11).
9. Ayatolahi SMT, Jafari P, Ghaem H. An evaluation of the quality of published clinical trials in Iranian medical journals during 2001 – 2004. *Journal of Babol University of Medical Science*. 2005; **7:** 64 – 70.
10. Uetani K, Nakayama T, Ikai H, Yonemoto N, Moher D. Quality of reports on randomized controlled trials conducted in Japan: Evaluation of adherence to the CONSORT statement. *Inter Med*. 2009; **48:** 307 – 313.