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Research Note

Quality Assessment of Randomized Controlled Trials in Shiraz University of Medical Sciences

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ABSTRACT

Randomized Controlled Trial (RCT) is scientific investigations that evaluate the safety and efficacy of new drugs or therapeutic procedures by using human subjects. This study aimed to assess the quality of RCT reports at Shiraz University of Medical Sciences (SUMS) from 2014 to 2016. A systematic search was done in international databases with the keyword "SUMS" covering the three years yielding 9124 articles. Eventually, 120 articles were selected out of 540 RCT-based articles through proportional stratified sampling. We used the 2010 Consolidated Standards of Reporting Trials (CONSORT) statement beside the Jadad scale to assess the quality of reports. We used the Pearson Correlation to investigate probable correlations between the CONSORT and Jadad mean scores and the Analysis of Variance (ANOVA) test to find the difference in the quality assessment tools in other studied variables. Among the selected articles, the average number of applicable reported items was 71.4 (59.5%) in the CONSORT 2010 checklist and 64 (53.4%) in Jadad. Among these RCTs, 55 (45.8%) had a high quality with Jadad scores ≥ 3 points. In addition, CONSORT and Jadad mean scores were significantly correlated (P <0.001, r: 0.808). We found no change in the mean score of CONSORT (P=0.788) or Jadad scale (P=0.492) over these three years. While the number of RCTs has gradually increased in these years, the quality of these reports has remained unchanged. Thus, national medical academics should make more efforts to conduct high-quality studies to ensure an appropriate study design.

Keywords: Randomizes controlled trial, CONSORT, Jadad, Quality assessment, SUMS, Iran.

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INTRODUCTION

RCTs are scientific investigations that evaluate the safety and efficacy of new drugs or therapeutic procedures by using human subjects. The results generated by these studies are considered the most valuable data in the area of evidence-based medicine.[1,2] Adequate quality in the study design, implementation and reporting is substantial in obtaining reliable results for application in clinical interventions. RCTs are often known as the gold standard for clinical trials.[3]

Proper randomization, after assessing the participants for eligibility and inclusion criteria and prior to the intervention, will yield meaningful benefits such as reducing allocation bias and balancing, both known and unknown prognostic factors.[4] This will help the researchers to explore any effects in the treatment group versus the control group while adjusting for other variables, leading to a correct decision regarding the adequacy and competence of the intervention.[5]

Therefore, a number of scientists and editors attempted to develop a package to help researchers to improve their trial design.[6] The outcome was the CONSORT statement, which includes a checklist of essential items that should be considered in reporting RCTs and a diagram to certificate the flow of participants through the trial in order to improve its quality. It was first published in 1996 and updated in 2001 and 2010, enabling the readers to understand a trial's design, conduct, analysis and interpretation and also helping them to assess the validity of the results.[5]

In addition, the Jadad scale sometimes referred to as the Oxford quality scoring system, is the most popular instrument worldwide to facilitate the independent assessment of the methodological quality of a clinical trial.[7,8]

Nevertheless, the literature contains many articles with poor design, methodology and analysis, even from academic sources, which will compromise scientific evidence.[9] Ascertaining the accuracy of the methodology is an indispensable factor in choosing studies for publication. Thus, evaluation of the quality of RCTs is essential, as the suboptimal quality of trials will negatively influence the researchers' understanding of evidence and consequently affect the scientific ranking of universities.[10] Besides, Iran has had a good scientific growth in the recent decade and has raised the number of Iranian RCTs published in prestigious journals. By the year 2014, there has been an ordinary growth in Iranian's research. Since 2014, rapid growth in scientific products, including RCTs, which were mainly conducted in medical universities of science, has been observed.[10,11] It is important to investigate that rather than the quantitative increase of RCTs, whether the quality of the reports has increased or not. Therefore, we decided to investigate the quality and degree of confidence in the RCTs published throughout 3-years (2014 to 2016), using the CONSORT 2010 and Jadad scales to find out how the items of these two scales have been used.

MATERIALS AND METHODS

Search strategy: A systematic search was performed in the international databases including Scopus, Web of Science, Embase, PubMed, Cochrane Library and national databases such as Science Information Database (SID), Iran Medex and Magiran with the keyword "Shiraz University of Medical Sciences" covering three years from 2014 to 2016.

Selection of RCTs

Out of 9124 articles returned from the search, 4827 duplicate reports were excluded from the study. The design of all the articles was checked by two independent reviewers who were blinded to the authors and the journals in which they were published. They identified all eligible articles with randomly assigned participants in an experimental or a control group to conduct RCTs.[3] The following article types were considered ineligible for the current study: trials other than RCTs (non-RCT studies, experimental studies, *in vitro* studies, etc.); case-control, cohort, cross-sectional, qualitative and methodological studies; editorials, short communications; case reports, case series; and all types of reviews. Considering the similar studies and comparing proportions formula. Eventually, 120 articles were selected out of the remaining 540 RCT-based articles through proportional stratified random sampling with a design effect of 1.5, a confidence level of 95% and Number of Error of 10%.[12,13] Each selected article was assigned an identification code. The selected RCTs were assessed by two researchers (M.B and M.H) independently. First, a random sample of 12 RCTs (10% of all included RCTs) was cross-checked to reach an agreement for unambiguous allocation of

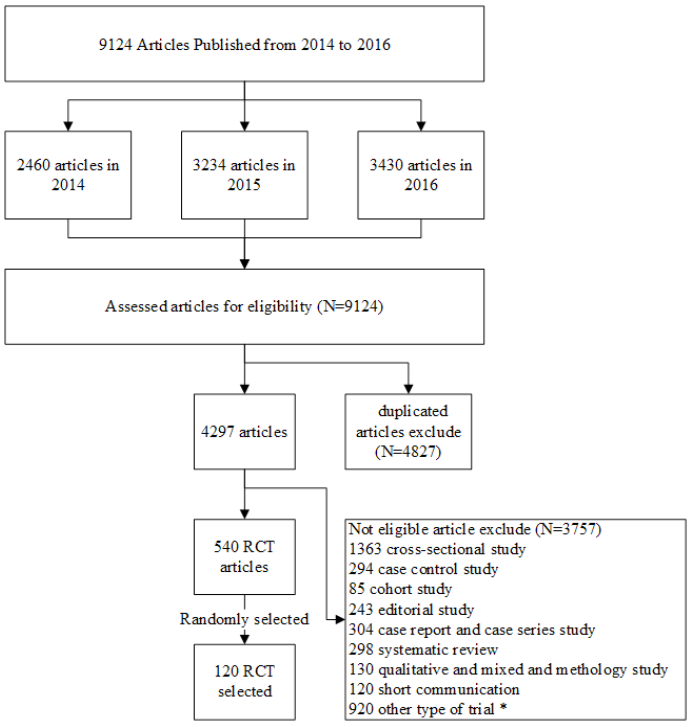

Figure 1: Flow diagram for selection of articles for inclusion in systematic review.
* Other types of the article include experimental studies, *in vitro* and non-RCT studies.

the checklist items.[14] Any uncertainty regarding the correct assignment was clarified with a third researcher (M.M). The inter-rater reliability was assessed for these random samples with a mean intraclass correlation coefficient of 90% [95% CI: 67.20, 97.50] and *P*-value < 0.001. After achieving acceptable concordance in appraising, the articles were assessed based on both CONSORT and Jadad scores. To minimize the selection bias, the articles without free access were purchased. In addition, the researchers were blinded to the authors and journals during the assessment process (Figure 1).

CONSORT statement 2010

The latest version of the CONSORT statement includes a checklist of essential items in five sections: Title and abstract, introduction, method, discussion and other information. Ambiguous items have been clearly explained in updated guidelines for reporting parallel group randomized trials–CONSORT 2010 Explanation and Elaboration.[4] All CONSORT items were weighted equally. If the item was mentioned in the proper section of the article, one point was assigned; if the item was not mentioned, zero was assigned. Items which were not applied were recorded as missing. The mean and frequency were calculated for each CONSORT item. The average score was calculated for applicable items

in the studied articles. Also, we calculated the mean score for each studied articles.

Jadad scale

The Jadad scale is the most frequently used instrument for evaluating and scoring the quality of RCTs literature due to its accessibility, completeness and its known reliability. In this study, the Jadad scale was used alongside the CONSORT checklist to identify the probable relationship between CONSORT 2010 and improvement of the quality of reports. Jadad scale has a maximum score of five: two points for randomization, two for blinding and one for the dropout objective. If the RCT-based report only mentioned randomization and blinding without any explanation, one point was allocated to each category. One additional point is assigned for an appropriate description of randomization and blinding. However, if the description of randomization and blinding is inappropriate, one point is deducted. If the fate of all patients in the trial is known, one point is assigned. A total score of ≥ 3 points demonstrates high quality, while a score of ≤ 2 points is considered to show low quality. Nevertheless, for studies where double-blinding is not possible, a total score of ≥ 2 points is considered as high quality.[15]

Determinants of report quality

In addition to the above-mentioned points, we collected further information about each article in order to identify probable variables that may influence the efficacy of reporting RCTs. These variables include the academic rank of the first author, number of authors, year of publication and field of study including medicine, nursing and midwifery, dentistry and others (physical education, medical education, biology, pathology, biochemistry, anatomy, physiology and pharmacology). In addition, journal metrics of published RCTs were assessed, namely the number of citations, Latest Impact Factor (LIF), Latest Source Normalized Impact per Paper (LSNIP), Latest Impact Per Publication and Latest SCImago Journal Rank.

Statistical analysis

For summary statistics, we calculated the mean and standard deviation in addition to reporting frequency and percentage. We used Pearson's rank correlation to analyze the correlation between the respective journal metrics and adherence to the CONSORT items. One-way analysis of variance (ANOVA) and LSD *post hoc* test were used to compare and analyze the respective scores obtained by each assessment tool. SPSS, version 18.0, was used for all statistical analyses and a P value <0.05 was considered as statistically significant. The compounded annual growth rate was calculated.[16]

Limitation: One of the limitations of this study was that our analysis was limited to published studies and therefore, it is potentially subject to publication bias.

RESULTS

From 2014 to 2016, the number of published RCTs in each year was 138, 156 and 246, respectively. The average number of RCTs reports increased over time with an annual growth rate of 21.25% over these three years.

The mean score of CONSORT 2010 checklist for RCTs published between 2014 and 2016 was 0.65 ± 0.13 and the frequency of the reported item was 71.4 (59.5%) in the selected 120 articles. In the introduction section, item 2a (mentioning scientific background and explanation of rationale) and item 2b (specific objectives or hypotheses); in the method section, item 5 (the interventions for each groups with sufficient details to allow replication) and item 6a (definition of pre-specified primary and secondary outcome measurement); and in the result section, item 17a (results of each group with estimated effect size) were reported in all 120 RCTs. Among the items of CONSORT 2010 checklists, items 3b (important changes in trial design), 6b (any changes in trial outcome) and 14b (why the trial stopped or ended recruitment) did not apply to any of the articles investigated. The average Jadad score was 2.58 ± 1.58 for the included studies. Among these RCTs, 55 (45.8%) had a high quality with Jadad scores ≥ 3 points. Randomization was reported in 95.8% of the articles; however, only 38.4% of them mentioned double blinding in their reports. Table 1 presents the frequency and mean scores of different sections of the CONSORT 2010 checklist and Jadad scale.

We found a statistically significant relationship between quality assessment means and LIF and LSJR. According to the results, articles with higher CONSORT and Jadad scores were published in journals with higher LIF and LSJR (Table 2).

Another finding was a statically significant positive correlation between CONSORT and Jadad mean scores (P <0.001, r: 0.808). Among the RCT-based articles published from 2014 to 2016, 43.3% belonged to clinical medicine, 30.8% to basic medical science, 14.2% to dentistry and 11.7% to nursing and midwifery. The highest CONSORT mean score (0.69 ± 0.13) and Jadad mean score (0.66 ± 0.33) belonged to medical field trials, while the lowest scores belonged to basic medical science trials (0.57 ± 0.11 in CONSORT and 0.33 ± 0.19 in Jadad score). As presented in Table 3, there were statistically significant differences observed between the fields of study. The *post hoc* test revealed that studies in the field of clinical medicine (P < 0.001 and MD = 0.12), nursing and midwifery (P < 0.001 and MD = 0.14) had statically significant higher

Table 1: Frequency and mean score of reported items of different sections of CONSORT 2010 checklist and Jadad scale.

Topic	item number	Frequency of reported item N (%)	Mean score* ±SD N (%)
Title and abstract	1a	32 (26.7)	0.27±0.44
	1b	103 (85.8)	0.86±0.35
Total		67.5(56.2)	
Introduction			
Background	2a	120(100.0)	1±0.00
Objective	2b	120(100.0)	1±0.00
Total		120(100.0)	
Method			
Trial design	3a	35 (29.1)	0.29±0.46
Participants	4a	117 (97.5)	0.98±0.16
	4b	111 (92.5)	0.93±0.26
sample size	7a	26 (21.6)	0.22±0.41
	7b	10 (8.4)	0.83±0.39
Randomization:			
Sequence Generation	8a	45(37.5)	
	8b	28(23.4)	0.38±0.49
Allocation concealment mechanism	9	13 (10.8)	0.23±0.42
Implementation	10	25 (20.8)	0.11±0.31
Blinding	11a	45 (37.5)	0.21±0.41
	11b	87 (72.5)	0.38±0.49
Statistical methods	12a	117(97.5)	0.86±0.35
	12b	39 (32.5)	0.98±0.16
Total		53.7(44.7)	0.89±0.32
Results			
Participant flow	13a	110 (91.7)	0.92±0.28
	13b	51 (42.5)	0.85±0.36
Recruitment	14a	110 (91.7)	0.94±0.24
Baseline data	15	72 (60.0)	0.67±0.47
Numbers analyzed	16	92 (76.7)	0.77±0.42
Outcomes and estimation	17b	17 (14.1)	0.14±0.35
Ancillary analyses	18	36(30.0)	0.80±0.40
Harms	19	39 (32.5)	0.34±0.48
Total		64.6(53.8)	
Discussion			
Limitations	20	72(60.0)	0.60±0.49
Generalizability	21	100 (83.4)	0.60±0.49
Interpretation	22	119 (99.1)	0.99±0.09
Total		97.0(80.8)	
Other information			
Registration	23	38 (31.7)	0.32±0.47
Protocol	24	53 (44.2)	0.44±0.50
Funding	25	81 (67.5)	0.59±0.49
Jadad score			
Randomization		115 (95.8)	0.96±0.20
appropriate method of randomization		56 (46.7)	0.47±0.58
Blinding		46 (38.4)	0.38±0.49
appropriate method of blinding		40 (33.4)	0.34±0.59
The fate of all patients in the trial is known.		63 (52.5)	0.51±0.50

*mean score is between zero (not reported) and one (reported).

mean CONSORT scores compared to basic medical science articles.

The median number of citations for all articles was four. The median number of citations has increased during the period of this study from three to five, although the variation in a number of citations had no statically significant correlations with quality of reports (P = 0.193for CONSORT mean score and 0.224 for Jadad mean score).

In 81 articles (67.5%), the first author was a faculty member. The CONSORT mean score was 0.64 ± 0.13 for articles with a faculty member as the first author and 0.65 ± 0.13 for the other articles.

The median number of authors was four in all selected articles. Articles with fewer than four authors had a mean CONSORT score of 0.64 ± 0.14 and Jadad score of 0.49 ± 0.35. Moreover, 47.5% of the articles had more than four authors with a mean CONSORT score of 0.65 ± 0.12 and Jadad score of 0.57 ± 0.33. We found no significant correlation between the mean quality assessment scores and the number of authors. Furthermore, we found no statistically significant changes in Jadad and CONSORT mean scores over these three years (P = 0.492 and 0.788, respectively) (Table 3).

DISCUSSION

Although the number of RCTs published from 2014 to 2016 has gradually increased, the mean score of CONSORT 2010, as well as the Jadad score, has not changed significantly over these three years. Also, inadequate reporting of the trial methodology is a critical problem in this evaluation. The small number of double blinded reports and lack of methodological details described for concealment of allocation preclude high-quality evaluation. Although citations have improved in number over these three years, we found no significant relationship with the quality of reporting. There was a significant relationship between journal metrics and the report quality of the trials. Furthermore, the CONSORT and Jadad scores were significantly higher in medicine and nursing and midwifery fields than basic medical science articles.

The average reporting percentage for the "title and abstract" section was 56.2%. We found that 26% of the articles were identified as randomized trials in the title, which is in line with

Table 2: Correlation of CONSORT and Jadad mean score with journal metrics.

Journal metrics	CONSORT mean score		Jadad mean score	
	R	*P*-value	R *	*P*-value
Last Impact Factor (LIF)	0.381‡	0.038	0.426†	0.019
Last SCImago Journal Rank (LSJR)	0.328 ‡	0.019	0.492‡	<0.001
Last Source Normalized impact per Paper (LSNIP)	0.111	0.474	0.416 ‡	0.004
Last Impact Per Publication (LIPP)	0.186	0.210	0.354†	0.018

* Pearson correlation test

† Correlation is significant at the level 0.01.

‡ Correlation is significant at the level 0.05.

Table 3: Factors associated with quality of RCTs.

Independent variable*	Frequency N (%)	CONSORT Mean score Mean±SD	Jadad Mean score Mean±SD
Field of study			
Clinical medicine	52(43.3)	0.69±0.13	0.66±0.33
basic medical science	37(30.8) 17(14.2)	0.57±0.11	0.33±0.19
dentistry	14(11.7)	0.62±0.12	0.49±0.41
Nursing and Midwifery		0.71±0.08	0.64±0.39
p-value±		<0.001	<0.001
Year of publication			
2014	35(29.2)	0.64± 0.13	0.48±0.31
2015	32(26.7)	0.66 ±0.14	0.58±0.32
2016	53(44.2)	0.64 ±0.14	0.53±0.38
p-value		0.788	0.492
Number of citation			
≤4	66(55.0)	0.66±0.12	0.56±0.34
>4	54(45.0)	0.63±0.14	0.48±0.35
p-value		0.193	0.224
Academic rank of first author			
Faculty member	81(67.5)	0.64±0.13	0.53±0.36
Not faculty member	39(32.5)	0.65±0.13	0.52±0.31
p-value		0.749	0.852
Number of authors			
≤4	63(52.5)	0.64±0.14	0.49±0.35
>4	57(47.5)	0.65±0.12	0.57±0.33
p-value		0.629	0.190

* One-way ANOVA, Chi-square test. The mean difference is significant at the 0.05 level.

± *Post Hoc* tests was performed

two similar studies.[17,18] Clear and sufficiently detailed abstracts are essential because readers often discern a trial based on such information. Furthermore, some readers use the abstract as a screening tool to decide whether or not to read the full article; therefore, the authors should use a structured summary to accurately report the contents of the full article. To ensure that a study is suitably indexed and simply identified, authors should use the word 'randomized" in the title to show that the participants are randomly assigned to groups.

In this study, all articles reported the introduction section correctly. Most reports of RCTs provide sufficient information about the objectives and hypotheses of the trial.[18]

Among the studied articles, 29% explained the trial design, such as the parallel group or factorial and the conceptual framework, such as superiority or non-inferiority. The word "design" is often applied to refer to all aspects of how a trial is planned. Inconsistent with our findings, Ana and colleagues conducted a study to evaluate CONSORT items for reporting

quality in the top ten journals of critical care medicine in 2011 and stated that 85% of articles report the design of the trial.[14] Similar to other studies, none of the articles in our study reported item 3b, which may be due to the possibility that no paramount changes were made to the methods after the trial started.[19] Likewise, in other studies, most articles in our study reported the eligibility criteria for participants, settings and locations where the data were collected.[20,21] The information on the settings and locations is very important for evaluating the applicability and generalizability of the trial findings. Thus, every author should report the type of settings. Obviously, all articles, regardless of their type, should describe the interventions with adequate details so as to allow the researchers to use the methodology of the study and apply their intervention or design in their research. In this study, like previous reports, all articles reported sufficient details about their design.[22] All the studied articles completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed. Nevertheless, a review has reported that nearly half of the journal articles describing RCTs had an unexplained disagreement in primary outcomes.[23] Only one-fifth of the articles described how the sample size was determined. Determining the method of calculation of sample size is very crucial for defining the balance between medical and statistical considerations.[24]

In this study, only 45 articles described sufficient information to assess the methods of sequence generation and the probability of bias in the process of dividing into groups and only 28 reported the type of randomization and details of any restriction. Most of the articles (90%) did not describe their allocation concealment mechanism; similarly, a study by You *et al*. reported less than 15% positive rate in 26 RCTs on scalp acupuncture for the treatment of vascular dementia.[20] Also, Kim *et al*. reported allocation concealment in only 5.6% of 146 RCTs addressing acupuncture in the Korean literature.[25] In contrast, the study by Karpouzis *et al*. on the quality of reporting in chiropractic and the study by Fung *et al*. respectively reported 87% and 83% allocation concealment.[19,21] A previous study showed that trials in which the allocation sequence had been inadequately or vaguely concealed had larger estimates of treatment effects than trials which reported it sufficiently.[26] Although the blinding status has an important effect on the validity of trails, item 11a was reported in only 37% of the articles. A study by Haahr *et al*. showed insufficient blinding; for instance, one in every five trials was reported as double-blind, but they did not correctly blind the participants, healthcare providers, or data collectors.[27]

In our study, most parts of the results section had high scores, but only 14% of them described the primary and secondary outcome, estimated effect size and its precision which is similar to previous studies.[19] For each outcome, the study results should be reported as a summary of the outcome in each group, together with the contrast between the groups, known as the effect size. Moreover, in recent years, most journals strongly encourage reporting the confidence intervals.[28]

The World Health Organization states that "the registration of all interventional trials is a scientific, ethical and moral responsibility".[29] With registering a randomized trial, authors typically report a minimal set of details and obtain a unique trial registration number. If authors could not register their trial, they should clearly state it as well as the reasons.

There are various types of qualitative assessment tools for RCTs, including Campell, Moher, Chalmers, Jadad, van Tulder, Newell's and Cochrane and CONSORT checklist 2010.[30,31] Particularly, the Jadad scale has superiority in the comprehensibility of the assessment questions and ease of assessment performance, while the CONSORT checklist 2010 evaluates how the articles are reported. Consequently, further analyses were performed using Jadad to supplement. We did not find any discrepancy in the qualitative analysis outcomes of RCTs using two different tools in this study, although another study reported variations in the quality of reports by different tools.[15]

Relationship of the amount of adherence of CONSORT to clinical reporting with journals metric is a novel issue which has been rarely reported in the literature. This study revealed the significant correlation of most journal metrics with CONSORT and Jadad scale Iver and his co-workers found that higher impact journals tended to score better in most reporting and methodological criteria. It seems reasonable that in trials published in higher impact factor journals, the reported criteria had absolute improvement after the CONSORT extension was published.[32]

In this study, we assessed the RCTs published by a specific academic university (SUMS) for the first time, so the novelty of the study is approved. The strength of this survey was the simultaneous use of two tools to assess the quality of the articles. Suggestions for qualitative improvement of medical research in this specific University of Medical Sciences are a significant contribution of this study. Performance of randomized controlled trials under the supervision of methodologists alongside the establishment of rules will contribute to the enhance the quality of the reports.

CONCLUSION

Adequate reporting of RCTs allows for easy determination of the RCT quality, which is important because RCTs of poor quality may exaggerate the effects of treatment and potentially lead to erroneous conclusions. While the number of RCTs has gradually increased over time, the quality of these reports has remained unchanged. Therefore, national medical academics

should make more efforts to conduct high-quality studies to ensure appropriate randomization, double blinding, the inclusion of allocation concealment and study design.

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CONFLICT OF INTEREST

Confirming that there are no known conflicts of interest associated with this publication and there has been no significant financial support for this work that could have influenced its outcome.

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