Original Article

Evaluation of reporting of CONSORT flow diagrams in randomized controlled trials in a national and international pharmacology journal

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Abstract

Objective: To evaluate and compare the reporting of consolidated standard of reporting trial (CONSORT) flow diagrams in randomized controlled trials (RCTs) published in a national and international pharmacology journal.

Methods: RCTs in an international pharmacology journal, European Journal of Clinical Pharmacology (EJCP), and a national journal, Indian Journal of Pharmacology (IJP), published from January 2014 to July 2016 were evaluated for reporting and completeness of CONSORT flow diagrams. A total of 138 articles (EJCP = 90; IJP = 48) were analyzed and compared.

Results: Of 138 RCTs analyzed, 90 were from EJCP and 48 were from IJP. 76.6% (69/90) articles from EJCP and 37.5% (18/48) articles from IJP had reported the CONSORT flow diagram. Of these, 95.5% (66/69) had assessed for eligibility in EJCP and 88.8% (16/18) had reported the same in IJP. The number of participants excluded was reported in 86.9% (60/69) flow diagrams in EJCP and 83.3% (15/18) in IJP. 82.6% (57/69) flow diagrams in EJCP and 77.7% (14/18) in IJP had mentioned the details of randomization. Allocation of intervention was reported in 91.3% (63/69) flow diagrams in EJCP and 88.8% (16/18) in IJP. 60.8% (42/69) flow diagrams in EJCP and 44.4% (08/18) in IJP had mentioned the details of follow-up of participants. 95.5% (66/69) flow diagrams in EJCP and 94.4% (17/18) in IJP had mentioned details about analysis.

Conclusion: In spite of both the journals, IJP and EJCP endorsing the CONSORT statement, a significant difference in the reporting of CONSORT flow diagrams in RCTs can be noted. The quality of reporting can be improved by stringent publication guidelines by the editors.

Keywords: EJCP, IJP, Thomas reuter impact factor

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INTRODUCTION

The randomized controlled trial (RCT), considered to be a gold standard in evaluating effectiveness of healthcare interventions, is now widely recognized following the movement of evidence-based medicine.[1-3]

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The published RCT report should maintain the highest possible standard as it not only can have powerful and immediate impact on patient care but also removes the investigator bias in allocation of participants.[2,4]

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Interpretation of RCT results becomes difficult, if not impossible, with inadequate reports causing biased results to receive false reliability.[5] Thus, adequate reporting is essential because the readers need and deserve to know the quality of methods to make informed judgment regarding the validity of clinical trial.[2,6]

Previous studies indicate that reports of low-quality RCTs, compared with reports of high-quality ones, overestimate the effectiveness of interventions by about 30% across the variety of health care conditions.[6,7]

That lack of adequate reporting fueled the development of consolidated standard of reporting trial (CONSORT) statement in 1996[3,8] and its revision 5 years later.[3,9]

The aim of this study is to evaluate the reporting of CONSORT flow diagram in RCT in pharmacology journals.

METHODS

Data source

We selected two CONSORT endorsing pharmacology journals, Indian Journal of Pharmacology (IJP), a national, and European Journal of Clinical Pharmacology (EJCP), an international journal, with Thomas Reuter impact factor 0.902 and 2.32, respectively.

We conducted a search to identify RCTs published in IJP and EJCP between January 2014 and July 2016. Moreover, the website used to access was http://www. ijp-online.com/for IJP and http://www.springer.com/biomed/pharmacology+%26+toxicology/journal/228 for EJCP.

Study selection

RCTs of preventive and therapeutic interventions were selected. We included reports in which the allocation of participants to intervention was described as random, randomly allocated, randomized, or randomization. Other study designs such as observational studies, economic analysis on RCTs, quasi-randomised trials, cluster randomized trials, diagnostic and screening tests, follow-up studies of previously reported RCTs, editorials, reviews, case reports, and letters were excluded.

Data extraction

Two reviewers underwent training in evaluating RCTs using CONSORT 2010 statement with special reference to CONSORT participant flow diagram. Both the reviewers extracted data from all included papers. Discrepancies were resolved by thorough discussion and also by using kappa scores.

The following is the information required to document the flow of participants through each stage of randomized trials according to item 13 of the CONSORT checklist as shown in Figure 1 and the same items were included in our checklist: enrolment–which includes participants assessed for eligibility and excluded before randomization, randomization, treatment allocation, follow-up details, and analysis.[10]

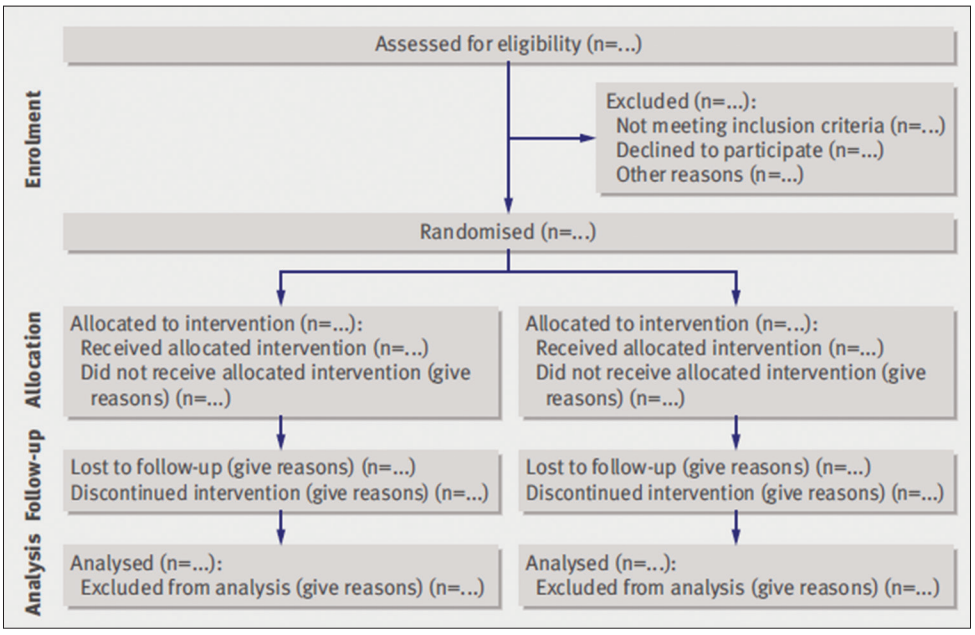

Figure 1: Flow diagram of the progress through the phases of parallel randomized trial of two groups (enrolment, intervention, allocation, follow-up, and data analysis)[10]

Table 1: The reported components of flow diagram

Component of Flow diagram	EJCP (*n*=90), *n* (%)	IJP (*n*=48), *n* (%)
Reported flow diagram	69/90 (76.67)	18/48 (37.5)
Assessed for eligibility	66/69 (95.5)	16/18 (88.8)
Excluded during enrollment	60/69 (86.9)	15/18 (83.3)
Randomization	57/69 (82.5)	14/18 (77.7)
Allocation to intervention	63/69 (91.3)	16/18 (88.8)
Loss to follow-up	42/69 (60.8)	8/18 (44.4)
Analysis	66/69 (95.5)	17/18 (94.4)

EJCP=European Journal of Clinical Pharmacology, IJP=Indian Journal of Pharmacology

Data analysis

Data for descriptive statistics were described as frequencies and percentages. The data were analyzed using Microsoft Excel version 2013 developed by Microsoft with Microsoft windows being the operating system.

RESULTS

Among the 138 RCTs included in the study, 65.2% (90/138) were published in EJCP and 34.7% (48/138) were published in IJP.

Of the 138 reports in the study, 63% (87/138) adhered to item 13 of the CONSORT checklist and reported the participant flow diagram. The reported component of flow diagram is shown in Table 1, 76.6% (69/90) in EJCP and 37.5% (18/48) in IJP reported participant flow diagram.

Details of enrolment

95.6% (66/69) in EJCP and 88.8% (16/18) in IJP had mentioned the participants assessed for eligibility in participant flow diagram.

86.6% (60/69) in EJCP and 83.3% (16/18) in IJP had reported the participants excluded during enrolment in flow diagram.

Details of randomization

82.6% (57/69) in EJCP and 77.7% (14/18) in IJP had reported about the participants randomized in the flow diagram.

Details of allocation

91.3% (63/69) in EJCP and 88.8% (16/18) in IJP had reported about participants allocated to intervention in the flow diagram.

Details of follow-up

60.8% (42/69) in EJCP and 44.4% (8/18) in IJP had reported about the participants who discontinued intervention or lost to follow-up.

Details of analysis

95.5% (66/69) in EJCP and 94.4% (17/18) in IJP had reported about the participants analyzed in the flow diagram.

DISCUSSION

The proportion of articles that included a CONSORT flow diagram varied widely across journals.

In this study, we have observed that majority of RCTs reported in two pharmacology journals, which had shown varied adherence to the flow diagram component of CONSORT guidelines. IJP (national) reported only 37.5% and EJCP (international) reported 76.67%.

A diagram showing flow of participants from enrolment to analysis is an important element of the CONSORT standards for reporting of clinical trial.

In more complex studies, it may be difficult for readers to discern whether and why some participants did not receive the treatment as allocated, were lost to follow-up, or were excluded from the analysis. Hence, knowing this information permits the reader to assess to what extent the estimated therapy might be underestimated in comparison with ideal circumstances.[10]

A study done by Uetani *et al*. in 2004 for the evaluation of adherence to CONSORT statement reported that only 6% of the articles had shown the flow diagram.[1]

A study done by Scott *et al*. in 2011 for completeness of reporting RCTs of three vaccine trials had reported only that only 43% had mentioned flow diagram among 70 publications.[11]

A study done by Jull and Aye in 2012 for quality of reporting RCTs in 15 leading nursing journals reported that 71.1% of the articles had shown participant flow diagram.[12]

Thus, the reporting of CONSORT flow diagram has improved in recent years after the CONSORT 2010 statement was laid down.[10]

We have assessed RCTs published from IJP (national) and EJCP (international); these journals have universal acceptance in the pharmacology research community. However, we still find that the reporting of flow diagram varies in two pharmacology journals which may be due to differences in the impact factors or might be because flow diagram takes up precious journal space, and the editor may sometimes feel that this space is better used otherwise. Our findings provide strong support for the idea that RCTs always should be published as full articles including a flow diagram. To the best of our knowledge, no studies have specifically evaluated the

adherence to the flow diagram component of CONSORT statement.

CONCLUSION

A participant flow diagram is highly recommended as per the CONSORT 2010 statement. In this study, we found varied adherence in IJP and EJCP to the flow diagram component of CONSORT guidelines.

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Conflicts of interest
There are no conflicts of interest.

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