Quality of a randomized-controlled trial- how to assess and improve reporting?

To the Editor,

A systematic literature review involves a critical appraisal of the available literature to answer a well-formulated research question. It follows a clearly defined protocol and has specific inclusion and exclusion criteria. A review is termed a meta-analysis when various statistical tests are used to summarize the results of this review. In systematic reviews and meta-analysis, various aspects regarding the quality of RCTs are investigated, such as the risk of bias within the studies, random sequence generation or allocation concealment that led to selection bias, heterogenicity in patients involved, methodology, intervention characteristics, the variable definition of endpoints of interest, and publication bias. Assessment of bias and quality of clinical trials is very important when a systematic review is being conducted. This is because trials that are not conducted with robust methodology can yield flawed results, which can interfere with evidence generation on analysis.[1]

The Consolidated Standards of Reporting Trials (CONSORT) was developed to improve the quality of reporting of a trial to facilitate reading and quality assessment of clinical trials by incorporating a 25-item checklist. The checklist provides information about the design, analysis, and interpretation of the trial. Although many RCTs have a CONSORT flow diagram, the article per se does not comply with the CONSORT checklist.[2]

The Jadad score is a popular scoring system used to assess the methodological quality of randomized controlled trials. It was described by a Columbian physician Alejandro "Alex" Jadad Bechara in 1996. Since then, the Jadad score has been used extensively to ascertain the methodological quality of a clinical trial that has fulfilled inclusion in a systematic review. Studies that fulfill the inclusion criteria are scored according to the presence of three key methodological features of clinical trials: randomization, blinding, and accountability of all patients, that is, withdrawal and dropouts. One point is scored for every "yes" answer to each of the first five items, and one point is deducted for a "yes" answer to either of the last two items, for an overall score of 0–5. If on analysis there were more than 4 points, it was considered to be of high quality; if the score was 3–4 points, it was considered to be of moderate quality; and if the score was less than 3 points, it was deemed low quality.[3,4]

Verhagen *et al*.[5] described the Delphi consensus method in 1998 which involves a list of criteria used to evaluate clinical trials and formulate recommendations based on consensus. It is a systematic process involving several rounds of discussion using questionnaires among selected panel members, especially in areas where it is difficult to arrive at conclusion or evidence is sparse or anecdotal. The Delphi process has now become quite popular as it has several applications. It can be used to evaluate current knowledge and find knowledge gaps, resolve controversies in management, formulate guidelines, develop assessment tools and indicators, and recommendations.[6] The positive aspects include having anonymous panelists, having controlled feedback, and interactive discussions involving several rounds. The negative aspects are that often the conclusion or recommendations are not based on robust evidence, thus affecting the reliability and the validity of the conclusions.

Imperfect methodology, conduct, and analysis introduce bias in a study, leading to flawed inferences, which in turn give a wrong message. In 2005, Cochrane collaborators introduced the risk of a bias assessment tool that assesses selection bias, performance bias, detection bias, attrition bias, reporting bias, and other biases. The present version of the tool assesses random sequence generation, allocation concealment, blinding of participants and persons involved, blinding of outcome assessment, incomplete outcome data, and other biases. The results are given as low risk, high risk, or unclear risk of bias.[7]

Several tools are available for assessing the quality of RCTs, the bias involved, and reporting checklist. However, it will be imperative if researchers adhere strictly to the checklist, follow a robust methodology, and address bias during study design.

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Conflicts of interest

There are no conflicts of interest.

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References

1. Berger VW, Alperson SY. A general framework for the evaluation of clinical trial quality. Rev Recent Clin Trials 2009;4:79-88.
2. Schulz KF, Altman DG, Moher D; CONSORT Group. CONSORT 2010 statement: Updated guidelines for reporting parallel group randomised trials. BMJ 2010;340:c332.
3. Hempel S, Suttorp MJ, Miles JNV, Wang Z, Maglione M, Morton S, *et al.* Empirical Evidence of Associations Between Trial Quality and Effect Size. Rockville (MD): Agency for Healthcare Research and Quality (US); 2011 Jun. [Table], Jadad Scale. Available from: https://www.ncbi.nlm.nih.gov/books/NBK56923/table/appendixes.app6.t1/. [Last accessed on 2021 Dec 18].
4. Jadad AR, Moore RA, Carroll D, Jenkinson C, Reynolds DJ, Gavaghan DJ, *et al.* Assessing the quality of reports of randomized clinical trials: Is blinding necessary? Control Clin Trials 1996;17:1-12.
5. Verhagen AP, de Vet HC, de Bie RA, Kessels AG, Boers M, Bouter LM, *et al.* The Delphi list: A criteria list for quality assessment of randomized clinical trials for conducting systematic reviews developed by Delphi consensus. J Clin Epidemiol 1998;51:1235-41.
6. Nasa P, Jain R, Juneja D. Delphi methodology in healthcare research: How to decide its appropriateness. World J Methodol 2021;11:116-29.
7. Higgins JP, Altman DG, Gøtzsche PC, Jüni P, Moher D, Oxman AD, *et al.* The cochrane collaboration's tool for assessing risk of bias in randomised trials. BMJ 2011;343:d5928.

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