

Short Communication



Is CONSORT a Risk of Bias Tool for Experimental Studies: A Big Misunderstanding

Ehsan Sarbazi¹ , Homayoun Sadeghi-Bazargani^{2*} ¹Road Traffic Injury Research Center, Tabriz University of Medical Sciences, Tabriz, Iran²Department of Statistics and Epidemiology, Faculty of Health, Tabriz University of Medical Sciences, Tabriz, Iran

Article Info

Article History:

Received: June 10, 2024

Accepted: July 2, 2024

ePublished: February 11, 2025

Keywords:

CONSORT, Clinical trials, Systematic reviews, Epidemiologic methods, Quality of reporting

*Corresponding Author:

Homayoun Sadeghi-Bazargani,
Email: homayoun.bazargani@gmail.com

Abstract

Introduction: In order to avoid bias in systematic reviews (SRs), the accuracy in selection of risk of bias (RoB) assessment tools is essential to obtain highest level of evidence for evidence-based decision making in health care. We aimed to review how ‘CONSORT statement’, as a reporting quality of randomized controlled trials, has been misused in recent SRs as a ROB tool.**Methods:** A mini-review was performed in international databases including PubMed, Google Scholar and hand-searches for published and unpublished literature from 2000 to 2021 and written in English. The following keywords: risk of bias, “Consolidated Standards of Reporting Trials”, CONSORT, “systematic review” were used. Citations were screened and those meeting our inclusion criteria were retained.**Results:** A total of 11 SRs were identified that misused CONSORT as a ROB tool, four of which were used only CONSORT as ROB tool. Different authentic magazines from various countries were recognized.**Conclusion:** The CONSORT statement aims to increase clarity and consistency of transparency of reporting in randomized controlled trials. It is quite essential to draw the attention of SR researchers, journal editors/reviewers as well as the reading audience to the fact that CONSORT statement CONSORT statement is not a ROB tool.

Introduction

Risk of bias (RoB) assessment supports establishing transparency of evidence synthesis and promoting the dissemination of robust evidence through systematic reviews (SRs).¹ Some of the RoB tools are general tools and some are developed for assessing RoB in specific study designs i.e. case-control studies.²⁻⁴

Regarding RoB, two other terms namely quality of conduct (QoC), and quality of reporting (QoR), are also used for appraising studies. Here we want to discuss a misunderstandings or lack of unanimous understanding about these three terms.⁴ Although these terms are highly associated, they are not necessarily the same. A study may have a high QoC, but low QoR and vice versa. There may also be situations in which a study with low RoB may suffer from poor QoR. Basically, QoC is closer to RoB than QoR, but even these two are not necessarily the same thing. Although experts often recommend a more robust approach to the assessment of study methods that focuses on the RoB rather than on quality per se,⁵ the most important issue would be to consider a suitable tool for assessing the issue of interest either quality or RoB.

Based on our experience it seems there is not a unanimous understanding of the three terms discussed above among some review researchers. QoR is commonly

assessed by CONSORT tool.⁶ Although, assessing QoR with CONSORT alongside the use of RoB tools supports a more comprehensive appraisal process,^{7,8} sometimes misunderstandings or at least impreciseness may occur. One such issue is to consider CONSORT as a Rob tool.

CONSORT improves the transparency of trial results. Misreporting avoidable issues has been demonstrated to impact the findings of SRs and meta-analyses, leading to research inefficiency.⁹ Thus this study has aimed to investigate how ‘CONSORT statement’, as a reporting quality of randomized controlled trials, has been misused in recent SRs as a ROB tool.

Methods: A mini-review was performed in international databases including PubMed, Google Scholar and hand-searches for published and unpublished literature from 2000 to 2021 and written in English. The following keywords: risk of bias, “Consolidated Standards of Reporting Trials”, CONSORT, “systematic review” were used. Citations were screened and those meeting our inclusion criteria were retained.

Results

Here we present some examples of such a misunderstanding in literature where some authors have inappropriately used CONSORT as a RoB tool (Table 1).

Table 1. Displays examples of published material which have listed CONSORT as a risk of bias assessment tool

Author	Review title	Listed tools	Sample statements	Locations	Source impact indicators	Source title
Lubans et al ¹⁰ 2012	A systematic review of the impact of physical activity programmes on social and emotional well-being in at-risk youth	CONSORT	Studies were assessed for ROB using criteria adapted from the CONSORT statement by two authors independently	Australia	Q3 SJR 2020=0.44 IF = 1.439	Child and Adolescent Mental Health
Cattuzzo et al ¹¹ 2016	Motor competence and health related physical fitness in youth: A systematic review	CONSORT and STROBE	ROB within studies was assessed using CONSORT and STROBE guidelines.	Brazil	Q1 SJR 2020=1.72 IF = 3.607	Journal of Science and Medicine in Sport
Foguet-Boreu et al ¹² 2016	Cardiovascular risk assessment in patients with a severe mental illness: a systematic review and meta-analysis	STROBE and CONSORT	The ROB was reported using STROBE and CONSORT criteria.	Spain	Q1 SJR 2019=1.44 IF = 2.704	BMC Psychiatry
Müller et al ¹³ 2016	The effectiveness of e- & mHealth interventions to promote physical activity and healthy diets in developing countries: A systematic review	CONSORT	The CONSORT checklist was used to assess the ROB of the included studies.	United Kingdom	Q1 SJR 2019=2.65 IF = 6.714	IJBNPA
Leye Benoist et al ¹⁴ 2016	Treatment of Dentin Hypersensitivity: A Systematic Review of Randomized Clinical Trials	CONSORT	Analysis of the quality based on CONSORT criteria showed that 10 articles were deemed to have a low ROB	Senegal	IF = 4.1	Journal of Dentistry and Oral Care Medicine
Fang et al ¹⁵ 2017	Nonmotor Symptoms in Amyotrophic Lateral Sclerosis: A Systematic Review	CONSORT, STROBE and GRADE	Apart from the excluded study, no other studies had a high ROB on STROBE/ CONSORT checklists or a very low quality of evidence using the GRADE criteria	United Kingdom	Q3 SJR 2020=0.41 IF = 2.627	Int Rev Neurobiol
Al-Sowaygh ¹⁶ 2019	Does Surgical Crown Lengthening Procedure Produce Stable Clinical Outcomes for Restorative Treatment? A Meta-Analysis	CONSORT and Cochrane Handbook	The ROB of CCTs was assessed based on the CONSORT statement.	Saudi Arabia	Q1 SJR 2019=0.89 IF = 2.187	J Prosthodontics
Spitz et al ¹⁷ 2020	Global gene expression profile of periodontal ligament cells submitted to mechanical loading: A systematic review	CONSORT and GRADE	The ROB and certainty of evidence (CoE) were assessed using a modified CONSORT checklist and the GRADE tool, respectively.	Brazil	Q1 SJR 2020=0.7 IF = 1.549	Archives of Oral Biology
Tan et al ¹⁸ 2020	Cyanoacrylate Dermal Closure in Spine Surgery: Systematic Review and Pooled Analysis	CONSORT and STROBE	ROB of included studies was assessed. A pre-specified set of 17 items pertinent to the methodological rigor of the included studies, as adapted from the CONSORT7 and STROBE8 guidelines were recorded.	Australia	Q1 SJR 2020=1.4 IF = 2.683	Global Spine Journal
Pagaduan et al ¹⁹ 2020	Can Heart Rate Variability Biofeedback Improve Athletic Performance? A Systematic Review	CONSORT	A study with a score of 0-2 is regarded as having a high ROB, 3-5 with medium ROB, and 6-8 considered as having low ROB (CONSORT, 2001).	Australia	Q2 SJR 2020=0.74 IF = 1.664	Journal of Human Kinetics

Other than these overt examples of the issue, there are also examples of ambiguity in RoB assessment methodology or tools.²⁰⁻²⁸ Moreover, some studies have stated in their Abstract that RoB had been assessed using CONSORT. However, the information provided in the full text of the article was different from what stated in Abstract.^{29,30}

Discussion: Although the review audience can themselves judge how appropriate is it to use CONSOERT as a ROB tool, as some of these articles are published in good journals, it is quite essential to draw the attention of SR researchers, journal editors/reviewers as well as the reading audience to the fact that QoR and RoB are not the same and separate specific tools should be used for assessing each of them.

This mini-review tries to re-inform the scientific audience, that although the quality reporting of clinical

trials is improved by the CONSORT tool, it may not be reasonable to use CONSORT as an alternative for available standard tools developed and validated for assessing RoB.

Conclusion

The CONSORT statement aims to improve clarity, consistency, and transparency in reporting randomized controlled trials. Researchers undertaking SRs should thoughtfully select tools aligned with their objectives to ensure reliability and foster trust in their published findings.

Authors' Contribution

Conceptualization: Ehsan Sarbazi, Homayoun Sadeghi-Bazargani.

Data curation: Ehsan Sarbazi, Homayoun Sadeghi-Bazargani.

Formal analysis: Ehsan Sarbazi.

Investigation: Ehsan Sarbazi.

Methodology: Ehsan Sarbazi, Homayoun Sadeghi-Bazargani.

Research Highlights

What is the current knowledge?

- CONSORT enhances the clarity of trial outcomes. Avoidable misreporting has been shown to influence the results of SRs and meta-analyses, contributing to research inefficiency.

What is new here?

- While the CONSORT tool enhances the quality reporting of clinical trials, it may not be appropriate to use it as a substitute for established standard tools designed and validated for assessing the ROB.

Project administration: Ehsan Sarbazi, Homayoun Sadeghi-Bazargani.

Resources: Ehsan Sarbazi.

Software: Ehsan Sarbazi.

Supervision: Homayoun Sadeghi-Bazargani.

Validation: Ehsan Sarbazi, Homayoun Sadeghi-Bazargani.

Visualization: Ehsan Sarbazi, Homayoun Sadeghi-Bazargani.

Writing—original draft: Ehsan Sarbazi.

Writing—review & editing: Ehsan Sarbazi, Homayoun Sadeghi-Bazargani.

Competing Interests

The authors declare no conflict of interest.

Data Availability Statement

All data generated or analyzed for this study are included in this published article.

Ethical Approval

Not applicable.

Funding

Not applicable.

References

- Higgins J, Chandler J, Cumpston M, Li T, Page MJ, Welch VJ, et al. *Cochrane Handbook for Systematic Reviews of Interventions*. Hoboken: Wiley; 2019. doi: [10.1002/9781119536604](https://doi.org/10.1002/9781119536604)
- Farrah K, Young K, Tunis MC, Zhao L. Risk of bias tools in systematic reviews of health interventions: an analysis of PROSPERO-registered protocols. *Syst Rev*. 2019; 8(1): 280. doi: [10.1186/s13643-019-1172-8](https://doi.org/10.1186/s13643-019-1172-8)
- Jarde A, Losilla JM, Vives J. Methodological quality assessment tools of non-experimental studies: a systematic review. *An Psicol*. 2012; 28(2): 617-28. doi: [10.6018/analesps.28.2.148911](https://doi.org/10.6018/analesps.28.2.148911)
- Ma LL, Wang YY, Yang ZH, Huang D, Weng H, Zeng XT. Methodological quality (risk of bias) assessment tools for primary and secondary medical studies: what are they and which is better? *Mil Med Res*. 2020; 7(1): 7. doi: [10.1186/s40779-020-00238-8](https://doi.org/10.1186/s40779-020-00238-8)
- Moher D, Jadad AR, Tugwell P. Assessing the quality of randomized controlled trials. Current issues and future directions. *Int J Technol Assess Health Care*. 1996; 12(2): 195-208. doi: [10.1017/s0266462300009570](https://doi.org/10.1017/s0266462300009570)
- Grant S, Mayo-Wilson E, Montgomery P, Macdonald G, Michie S, Hopewell S, et al. CONSORT-SPI 2018 explanation and elaboration: guidance for reporting social and psychological intervention trials. *Trials*. 2018; 19(1): 406. doi: [10.1186/s13063-018-2735-z](https://doi.org/10.1186/s13063-018-2735-z)
- Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomized trials. *Ann Intern Med*. 2010; 152(11): 726-32. doi: [10.7326/0003-4819-152-11-201006010-00232](https://doi.org/10.7326/0003-4819-152-11-201006010-00232)
- Tikka C, Verbeek J, Ijaz S, Hoving JL, Boschman J, Hulshof C, et al. Quality of reporting and risk of bias: a review of randomised trials in occupational health. *Occup Environ Med*. 2021; 78(9): 691-6. doi: [10.1136/oemed-2020-107038](https://doi.org/10.1136/oemed-2020-107038)
- Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S, et al. Reducing waste from incomplete or unusable reports of biomedical research. *Lancet*. 2014; 383(9913): 267-76. doi: [10.1016/s0140-6736\(13\)62228-x](https://doi.org/10.1016/s0140-6736(13)62228-x)
- Lubans DR, Plotnikoff RC, Lubans NJ. Review: A systematic review of the impact of physical activity programmes on social and emotional well-being in at-risk youth. *Child Adolesc Ment Health*. 2012; 17(1): 2-13. doi: [10.1111/j.1475-3588.2011.00623.x](https://doi.org/10.1111/j.1475-3588.2011.00623.x)
- Cattuzzo MT, Dos Santos Henrique R, Ré AH, de Oliveira IS, Melo BM, de Sousa Moura M, et al. Motor competence and health related physical fitness in youth: a systematic review. *J Sci Med Sport*. 2016; 19(2): 123-9. doi: [10.1016/j.jsams.2014.12.004](https://doi.org/10.1016/j.jsams.2014.12.004)
- Foguet-Boreu Q, Fernandez San Martin MI, Flores Mateo G, Zabaleta Del Olmo E, Ayerbe García-Morzon L, Perez-Piñar López M, et al. Cardiovascular risk assessment in patients with a severe mental illness: a systematic review and meta-analysis. *BMC Psychiatry*. 2016; 16: 141. doi: [10.1186/s12888-016-0833-6](https://doi.org/10.1186/s12888-016-0833-6)
- Müller AM, Alley S, Schoeppe S, Vandelandotte C. The effectiveness of e- & mHealth interventions to promote physical activity and healthy diets in developing countries: a systematic review. *Int J Behav Nutr Phys Act*. 2016; 13(1): 109. doi: [10.1186/s12966-016-0434-2](https://doi.org/10.1186/s12966-016-0434-2)
- Leye Benoist F, Niang SO, Faye B, Sarr M, Seck A, Ndiaye D, et al. Treatment of dentin hypersensitivity: a systematic review of randomized clinical trials. *J Dent Oral Care Med*. 2016; 2(2): 204. doi: [10.15744/2454-3276.2.204](https://doi.org/10.15744/2454-3276.2.204)
- Fang T, Jozsa F, Al-Chalabi A. Nonmotor symptoms in amyotrophic lateral sclerosis: a systematic review. *Int Rev Neurobiol*. 2017; 134: 1409-41. doi: [10.1016/bs.irn.2017.04.009](https://doi.org/10.1016/bs.irn.2017.04.009)
- Al-Sowaygh ZH. Does surgical crown lengthening procedure produce stable clinical outcomes for restorative treatment? A meta-analysis. *J Prosthodont*. 2019; 28(1): e103-9. doi: [10.1111/jopr.12909](https://doi.org/10.1111/jopr.12909)
- Spitz A, Christovam IO, Marañón-Vásquez GA, Masterson DF, Adesse D, Maia LC, et al. Global gene expression profile of periodontal ligament cells submitted to mechanical loading: a systematic review. *Arch Oral Biol*. 2020; 118: 104884. doi: [10.1016/j.archoralbio.2020.104884](https://doi.org/10.1016/j.archoralbio.2020.104884)
- Tan T, Rutges J, Marion T, Hunn M, Tee J. Cyanoacrylate dermal closure in spine surgery: systematic review and pooled analysis. *Global Spine J*. 2020; 10(4): 493-8. doi: [10.1177/2192568219861619](https://doi.org/10.1177/2192568219861619)
- Pagaduan JC, Chen YS, Fell JW, Wu SS. Can Heart rate variability biofeedback improve athletic performance? A systematic review. *J Hum Kinet*. 2020; 73: 103-14. doi: [10.2478/hukin-2020-0004](https://doi.org/10.2478/hukin-2020-0004)
- Annis A, Freitag MB, Evans RR, Wiitala WL, Burns J, Raffa SD, et al. Construction and use of body weight measures from administrative data in a large national health system: a systematic review. *Obesity (Silver Spring)*. 2020; 28(7): 1205-14. doi: [10.1002/oby.22790](https://doi.org/10.1002/oby.22790)
- Slotte S, Sääkslahti A, Kukkonen-Harjula K, Rintala P. Fundamental movement skills and weight status in children: a systematic review. *Balt J Health Phys Act*. 2017; 9(2): 115-27. doi: [10.29359/bjhp.09.2.11](https://doi.org/10.29359/bjhp.09.2.11)
- Kolahi J, Khazaei S. Assessment of blinding success among dental implant clinical trials: a systematic review. *Dent*

- Hypotheses. 2015; 6(4): 129-33. doi: [10.4103/2155-8213.170636](https://doi.org/10.4103/2155-8213.170636)
23. López-Medina MD, Linares-Abad M, López-Araque AB, López-Medina IM. Dry care versus chlorhexidine cord care for prevention of omphalitis. Systematic review with meta-analysis. Rev Lat Am Enfermagem. 2019; 27(3): e3106. doi: [10.1590/1518-8345.2695.3106](https://doi.org/10.1590/1518-8345.2695.3106)
24. Gupta AK, Daigle D. The use of low-level light therapy in the treatment of androgenetic alopecia and female pattern hair loss. J Dermatolog Treat. 2014; 25(2): 162-3. doi: [10.3109/09546634.2013.832134](https://doi.org/10.3109/09546634.2013.832134)
25. Ebrahimi A, Tayebi N, Fatemeh A, Akbarzadeh M. Investigation of the role of herbal medicine, acupressure, and acupuncture in the menopausal symptoms: an evidence-based systematic review study. J Family Med Prim Care. 2020; 9(6): 2638-49. doi: [10.4103/jfmpc.jfmpc_1094_19](https://doi.org/10.4103/jfmpc.jfmpc_1094_19)
26. Rathod S, Wanikar I, Paralikar A. Soft and hard-tissue changes after the placement of smart blood derivative platelet-rich fibrin into intrabony defects: a systematic review and meta-analysis with at least 9-month follow-up. J Int Clin Dent Res Organ. 2018; 10(2): 49-58. doi: [10.4103/jicdro.jicdro_10_18](https://doi.org/10.4103/jicdro.jicdro_10_18)
27. Zhai X, Wang Y, Mu Q, Chen X, Huang Q, Wang Q, et al. Methodological reporting quality of randomized controlled trials in 3 leading diabetes journals from 2011 to 2013 following CONSORT statement: a system review. Medicine (Baltimore). 2015; 94(27): e1083. doi: [10.1097/md.0000000000001083](https://doi.org/10.1097/md.0000000000001083)
28. McFarland LV, Goh S. Preventing pediatric antibiotic-associated diarrhea and *Clostridium difficile* infections with probiotics: a meta-analysis. World J Metaanal. 2013; 1(3): 102-20. doi: [10.13105/wjma.v1.i3.102](https://doi.org/10.13105/wjma.v1.i3.102)
29. Alkhawaldeh JM, Soh KL, Mukhtar FB, Ooi CP. Effectiveness of stress management interventional programme on occupational stress for nurses: a systematic review. J Nurs Manag. 2020; 28(2): 209-20. doi: [10.1111/jonm.12938](https://doi.org/10.1111/jonm.12938)
30. Tallarico M, Caneva M, Meloni SM, Xhanari E, Omori Y, Canullo L. Survival and success rates of different shoulder designs: a systematic review of the literature. Int J Dent. 2018; 2018: 6812875. doi: [10.1155/2018/6812875](https://doi.org/10.1155/2018/6812875)