

Requirements for Submission of CONSORT Guidelines at the time of Submission of Surgical Randomized Controlled Trials

The Journal of Gastrointestinal Surgery recognizes that properly designed, rigorously conducted, and properly analyzed randomized controlled trials (RCTs) represent the gold standard in evaluating surgical interventions. However, RCTs need methodological rigor. Past reviews of surgical RCTs have found fault in the majority of surgical RCTs published in recent years. Thus, the need for guidelines was recognized in the early 1990s, and the development of the original CONSORT (Consolidated Standards of Reporting Trials)¹ guidelines, and the original CONSORT Statement in 1996, was followed by two revisions, most recently in 2010. A further development was the initiation of the CONSORT extension targeting Non-Pharmacological Trials (NPTs)² covering a wide range of interventions including surgical procedures. The CONSORT NPT Statement takes into consideration special issues when assessing a variety of interventions, such as difficulties in blinding, the complexity of the intervention, the volume of cases at participating centers, and other factors affecting treatment effects. In keeping with the requirements of other surgical journals, the Journal of Gastrointestinal Surgery strongly encourages prospective authors to complete the CONSORT NPT checklist when submitting Randomized Controlled Trials for editorial review. This checklist is available at: <http://www.consort-statement.org/media/default/downloads/CONSORT%202010%20Checklist.pdf>

References:

1. Schulz KF, Chalmers I, Hayes RJ et al. Empirical evidence of bias: Dimensions of methodological quality associated with estimates of treatment effects in controlled trials. JAMA 1995; 273:408-412.
2. Boutron I, Moher D, Altman DG et al. Extending the CONSORT statement to randomized trials of non-pharmacological treatment: Explanation and elaboration. Ann Intern Med 2008; 148:295-309.



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