Improving the completeness and transparency of protocols and reports of randomized trials: SPIRIT 2025 and CONSORT 2025

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Professor Drummond Rennie, founder of the International Congress on Peer Review and Scientific Publication, lamented the widespread suboptimal reporting of randomized trials. He famously said, “the whole of medicine depends on the transparent reporting of clinical trials” (1). Reporting guidelines for randomized trials were introduced in 1994, CONSORT was published in 1996 and updated in 2001 and 2010. In 2013, SPIRIT was published to provide guidance to authors for reporting protocols of randomized trials. Access to trial protocols, trial registry records, and reports of completed trials, has become increasingly important when assessing trials for methodological and reporting biases.

We have updated SPIRIT and CONSORT. Both are simultaneously published as SPIRIT 2025 and CONSORT 2025 in multiple journals (2-11). These publications supersede all earlier versions of both checklists and should be the version of use by all prospective authors. To help harmonize the reporting of trial protocols and completed trials we merged the SPIRIT and CONSORT executive groups; worked to ensure common language and guidance across both guidances. We developed an expanded version of both checklists with bullet points to highlight key information from the SPIRIT 2025 and CONSORT 2025 explanation and elaboration (E&E) articles for each checklist item. This approach previously proved successful in training graduate students to use a writing aid tool (i.e., COBWEB) to improve the writing of methods sections of randomized trials (12). SPIRIT 2025 and CONSORT 2025 also incorporated some critical items from key SPIRIT and CONSORT extensions (Harms, Outcomes, Nonpharmacological treatments, and TIDieR [Template for Intervention Description and Replication]) in the hopes of reducing the burden of using multiple reporting guidelines for the same trial. Furthermore, we consolidated the SPIRIT and CONSORT websites into one (www.consort-spirit.org). Both checklists now include a new Open Science section that asks authors to report on trial registration, protocol availability, and plans for data sharing, and an item on patient and public participation. We hope these changes will enhance dissemination, use, and implementation. Interested users should read both Statements to familiarize themselves with other changes.

Along with both statements, we have also published updated SPIRIT 2025 and CONSORT 2025 E&E articles (13-14). For optimal use of both checklists, we recommend authors read the E&E articles alongside using the checklists. Both E&Es provide examples of good reporting and the rationale for each checklist item, as well as extensive references. For example, CONSORT 2025 now asks authors to report "Where and how the individual de-identified participant data (including data dictionary), statistical code and any other materials can be accessed" (checklist item 5). This request is based on considerable evidence that data sharing is uncommon in biomedical research (15) while the views of patients support sharing their data.

A recent audit (16) indicates that 262 reporting guidelines, including extensions, exist on the EQUATOR Network's library for a wide variety of preclinical and clinical study designs, types of data and other domains. Too many guideline extensions for trial protocols and completed trials likely introduce confusion and burden for authors. The SPIRIT/CONSORT executive plans on reducing the number of extensions. We have developed a 'new extension' request form, asking developers to describe several criteria as to why a new extension is needed. We will also advocate for better implementing of existing reporting guidelines instead of creating additional extensions for specific trial types.

The trade-off in developing a new clinical trial reporting guideline extension is the addition of more confusion and complexity to the process of using existing guidelines. For current trial extensions it is important to consider how best to bring them up to date to align with the new SPIRIT 2025 and CONSORT 2025 checklists. The SPIRIT-CONSORT executive plans on reaching out to extension developers to create plans for this updating.

Use of reporting guidelines improves the quality of reporting completed randomized trials (17) and protocols of such trials (18). Moreover, improving the reporting of research is an essential prerequisite (19) to tackling the ongoing problems of reproducibility. Using a reporting guideline may marginally increase the time to required

prepare a protocol or manuscript. However, it could save time in the overall publication process by enhancing the completeness and clarity of the information presented. In any case, reporting guidelines are important to help ensure a minimal threshold for adequate comprehensive and transparent reporting of research (20).

As journal endorsement of reporting guidelines continues to increase, the real litmus test is whether, and how, journals implement them. Some journals often use vague language that increases author confusion (e.g., ‘we encourage the use of reporting guidelines’). Similarly, it is not clear how endorsing journals monitor adherence to reporting guidelines. For example, does a journal staff member review all completed reporting, select some to review at random, or overlook them entirely?

Research performing organizations (e.g., universities, research institutes) do not have mandates for faculty or staff to use reporting guidelines. Unfortunately, many such organizations are focused on the quantity of publications to promote their ranking rather than the quality of their outputs. Research performing organizations could incentivize and reward the use of reporting guidelines. Similarly, funders do not appear to mandate the use of reporting guidelines in publishing the research that they fund (21). It is also time for journals to go beyond passive endorsement of SPIRIT and CONSORT and to more actively enforce their use for reporting protocols and completed trials. Such a policy would more strongly support adequate reporting of randomized trials for the benefit of the whole of medicine.

Declaration of interest

Professors Boutron, Hróbjartsson, and Moher declare being editorial board members of the journal.

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