An update to SPIRIT and CONSORT reporting guidelines to enhance transparency in randomized trials

Results from clinical trials can be deemed trustworthy only if they are properly conducted and their methods are fully reported. The SPIRIT and CONSORT checklists, which have improved clinical trial design, conduct and reporting, are being updated to reflect recent advances and improve the assessment of healthcare interventions.

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Well-designed and properly executed randomized trials provide the most reliable evidence on the benefits and harms of healthcare interventions. Ensuring transparent and complete reporting is essential in order to assess the reliability and reproducibility of randomized trials[1]. Attention has been drawn to problems with the entire research process, from the research questions being asked and the methods used to conduct research, through to how studies are reported[2].

Informative critical appraisal of the quality of randomized trials is possible only if their design, conduct and analysis are thoroughly and accurately reported. However, there is overwhelming evidence that the completeness of the reporting of randomized trials is suboptimal[3], which means that healthcare providers, patients and the scientific community cannot reliably distinguish research that is more trustworthy from research that is less trustworthy. The rapidly expanding number of COVID-19-related clinical trials has highlighted the urgent need for complete and timely reporting of study methods and results to inform patient care and public health policy. During the COVID-19 pandemic, a large 'living' (continually updated) systematic review showed that 43% of 251 trials did not report information related to the randomization process; half did not report complete information related to the beneficial effect; and 86% provided insufficient information on any harms[4].

Incomplete reporting

Trials with inadequate methods are associated with bias, especially exaggerated treatment effects. A study of 234 unique meta-analyses containing 1,973 trials found that intervention effect estimates were exaggerated in trials with inadequate or unclear random-sequence generation, inadequate or unclear allocation concealment, and/or lack of or unclear blinding[5]. Without a complete published description of the intervention, researchers are unable to replicate or build on research findings. This leaves clinicians, patients and other decision-makers unclear about how to reliably implement an effective intervention and apply the results of trials in clinical practice[6,7].

Without clear reporting of trial methods and results, readers are unable to judge the reliability and validity of trial findings and extract information for systematic reviews. For example, a study showed that 41% of randomized trials included in systematic reviews were at unclear risk of bias in at least one domain of assessment, mainly because of incomplete reporting[8]. Trial protocols are also important because this pre-specifies the methods used in the trial, such as the primary outcome, and thereby reduces the likelihood of undeclared post-hoc changes to the trial, such as outcome switching. Prevalent practices, such as unclear reporting of methods and primary outcome switching, result in a distortion of the evidence base[9].

Issues around poor reporting of research are arguably one of the aspects of research waste that is easiest to fix, as highlighted by Doug Altman in 1996, who pointed out that "readers should not have to infer what was probably done, they should be told explicitly"[10]. Efforts to improve the reporting of randomized trials gathered impetus in the mid-1990s (Box 1) and resulted in publication of the Standardized Reporting of Trials (SORT) Statement and Asilomar guidelines in 1994. Those initiatives then led to publication of the CONSORT (Consolidated Standards of Reporting Trials) Statement in 1996 (ref. [11]), which was revised in 2001 (ref. [12]) and last updated in 2010 (ref. [13]), along with an updated CONSORT Explanation and Elaboration article, with a strong pedagogical focus[14]. Similar problems with the lack of clear and transparent reporting of trial protocols led to the development of the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) Statement, published in 2013 (ref. [15]), and its accompanying Explanation and Elaboration document[16] that explained and illustrated the principles underlying the statement.

SPIRIT and CONSORT are evidence-based guidelines that comprise a checklist of essential items that should be included in protocols and primary reports of completed randomized trials, respectively, and include a diagram that documents the flow of participants through a trial. The statements provide guidance to authors on the minimum information that should be included in the reporting of trials in order to ensure that trial protocols and trial reports are clear, complete and transparent[13,14].

Box 1 | Timeline for development of the SPIRIT and CONSORT Statements.

1994: Alisomar guidelines published
1994: SORT statement published
1996: CONSORT statement first published
2001: Updated CONSORT statement published
2007: SPIRIT initiative launched
2008: EQUATOR network launched
2010: Updated CONSORT statement published
2013: SPIRIT statement published
2022–2023: SPIRIT–CONSORT update planned

Table 1 | Extensions to SPIRIT and CONSORT

Statement	Type	Extension	Stage
SPIRIT	Design	Early-phase dose-finding trials	In development
		Factorial trials	In development
		N-of-1 trials	Completed
		Pilot and feasibility trials	Completed
	Data	Patient reported outcomes	Completed
		Outcomes	In development
		Pathology	In development
CONSORT	Design	Adaptive designs	Completed
		Cluster trials	Completed
		Crossover trials	Completed
		Early-phase dose-finding trials	In development
		Factorial trials	In development
		Multicenter trials	Completed
		Non-inferiority and equivalence trials	Completed
		N-of-1 trials	Completed
		Pilot and feasibility trials	Completed
		Pragmatic trials	Completed
		Stepped-wedge cluster trials	Completed
		Trials using cohort and routinely collected data	Completed
		Within-person trials	Completed
	Data	Abstracts	Completed
		Equity	Completed
		Harms	Being updated
		Outcomes	In development
		Patient-reported outcomes	Completed
	Interventions	Non-pharmacological treatments	Completed

Impact of SPIRIT and CONSORT

The main impact of SPIRIT and CONSORT guidelines is their endorsement by journals, which has improved clinical trial reporting. This endorsement informs prospective authors of the degree of transparency and completeness journals expect from authors in their trial protocols and reports of completed trials. In 2012, a Cochrane review of 50 evaluations of 16,604 trials assessed the effect of journals' endorsement of CONSORT on the reporting of trials they publish. 25 of 27 CONSORT-related checklist items measured were more completely reported when a trial was published in an endorsing journal than when trials were published in non-endorsing journals[3].

CONSORT has been heavily cited[17], is listed among the top health research milestones of the twentieth century, according to the Patient-Centered Outcomes Research Institute[18], and is among the top 1% of all research articles by article-level metrics, as tracked by Scopus[13,19]. CONSORT 2010 has been translated into 13 languages, and SPIRIT 2013 has been translated into 7 languages. CONSORT and SPIRIT have received global endorsement by prominent editorial organizations, including the World Association of Medical Editors, the International Committee of Medical Journal Editorial and the Council of Science Editors, as well as by organizations such as the European Clinical Research Infrastructure Network and the pharmaceutical industry.

Updating the guidelines

SPIRIT and CONSORT have evolved over time (Box 1) and have been developed and led separately, which has resulted in misalignment between the two. The SPIRIT and CONSORT Executive Groups have recently merged to form one group with a common strategy for updates and extensions. The SPIRIT–CONSORT Executive Group is planning a major joint update of the SPIRIT 2013 and CONSORT 2010 Statements and the accompanying Explanation and Elaboration documents concurrently. It has been more than 10 years since the CONSORT Statement was last updated and 9 years since SPIRIT was published. It is vital that the guidelines be periodically updated to reflect methodological advancements and feedback from users; otherwise, their value and usefulness will diminish over time, rendering them no longer fit for purpose. In this era of increased transparency of clinical research and new evidence, it is more important than ever that SPIRIT and CONSORT remain current and relevant to end users.

The aim of updating the SPIRIT 2013 and CONSORT 2010 Statements together is to align reporting in both checklists and to provide users with consistent guidance in the reporting of trial design, conduct and analysis, from trial protocol to final publication. Streamlining and harmonizing the reporting process will improve usability and adherence, which will lead to more-complete reporting. SPIRIT and CONSORT have some overlap, particularly for methodological items related to trial design, and further alignment will facilitate usability and implementation, as well as being more efficient.

Several existing and emerging initiatives need to be considered during the update. For example, the TIDieR (Template for Intervention Description and Replication) Statement has argued for improvements to the completeness of reporting and, ultimately, the replicability of trial interventions[6]. The involvement of patients and the public in the design and conduct of health and social care research is now widely recognized as essential, so this involvement should be clearly reported in the trial protocol and in the trial results[20]. Data sharing of clinical trial results is evolving quickly and will be addressed in the updates; authors need to be aware of this changing landscape. Funders are starting to require explicit data-management plans and data-sharing requirements in grant applications, in addition to statistical analysis plans[21]. Journals are also starting to require data sharing of trial results, including individual de-identified participant-level trial data, before publication. As with previous updates of CONSORT, existing SPIRIT and CONSORT checklist items will be examined to revisit their wording and ensure their continuing completeness and scientific accuracy. For example, the CONSORT 2010 update added a new item that asked authors to specify how blinding was done. The item asking authors to explain how the success of blinding was assessed was deleted as part of the CONSORT 2010 update[14] because of a lack of evidence supporting this practice.

Table 2 | Process for updating SPIRIT 2013 and CONSORT 2010

Step	Process
1. Literature review	Conduct scoping review of comments on SPIRIT and CONSORT, including suggestions for modifications; develop database of the literature to identify new evidence relevant to reporting of randomized trials
2. Delphi survey	Conduct international Delphi survey to obtain views of a diverse range of stakeholders on potential changes and modifications to SPIRIT and CONSORT checklists
3. Consensus meeting	Establish consensus among a broad range of stakeholders on items to include in the updated SPIRIT and CONSORT checklists
4. Checklist and E&E revision	Revise and update the SPIRIT and CONSORT checklists and accompanying E&E documents; pilot the revised checklists
5. Dissemination and implementation	Create dissemination materials and run campaigns targeting those who can reach authors, such as journals, language professionals, and educators; create a new joint SPIRIT–CONSORT website, online training modules, and new patient-facing portal

E&E, Explanation and Elaboration.

SPIRIT is aimed at protocols of randomized trials, whereas CONSORT is aimed at primary reports of completed randomized trials with two-group parallel designs. A number of core extensions to SPIRIT and CONSORT have been developed to tackle the methodological issues associated with the reporting of different types of trial designs, data and interventions (Table 1). Additionally, applications of SPIRIT and CONSORT have been developed to interpret standard guidance in specific contexts, such as trials in specific disease areas or populations. However, the growing number of extensions is making their use and application increasingly burdensome for end users, which reduces the value of these tools. As part of the updating of SPIRIT and CONSORT, certain key extensions whose checklist items apply to all trials will be incorporated into the main SPIRIT and CONSORT checklists. This includes the CONSORT extension for the reporting of harms-related data in randomized trials[22], which is currently being updated, and a new SPIRIT and CONSORT extension for the reporting of outcomes in trial protocols and trial reports[23]. By incorporating checklist items from key extensions, a more comprehensive trial protocol and primary report will be established[24].

One of the challenges for the SPIRIT–CONSORT Group is how to better facilitate dissemination, endorsement and implementation to improve adherence to these guidelines and their extensions. The SPIRIT website (https://www.spirit-statement.org/) and CONSORT website (https://www.consort-statement.org/) encompass various initiatives aimed at improving the reporting of randomized trials. In 2020, more than 200,000 unique users visited the CONSORT website, and 73,000 visited the SPIRIT website. Funding has been secured to create a new joint SPIRIT–CONSORT website, with new resources aimed at researchers, journal editors and peer reviewers, that explains the main changes to the SPIRIT and CONSORT checklist guidance and how the updated guidance should be used.

The EQUATOR (Enhancing Quality and Transparency of Health Research) Network has established methods for developing reporting guidelines for health research; these will be used to update SPIRIT 2013 and CONSORT 2010 (ref. [25]), following methodology similar to that used to develop the recent CONSORT and SPIRIT extensions. The update will happen in five stages, outlined in Table 2. A wide range of stakeholders with broad geographical representation will be included in the update process in order to ensure implementation of and adherence to the new guidelines. Stakeholders will include clinical trial researchers and clinicians, as well as representatives from funding bodies, ethics committees, medical journals, regulatory agencies and industry. The views of patients and the public are also essential, as research would not be possible without them, and they are directly affected by the results of clinical trials. Stakeholders who are interested in this project and who wish to take part in the Delphi survey process should register their interest via the SPIRIT–CONSORT project website (https://www.ndorms.ox.ac.uk/octru/methodology-research#spirit-consort-update-project). ❐

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Author contributions

S.H., I.B., A.-W.C., A.H., K.F.S. and D.M. were responsible for the concept; S.H., I.B., A.-W.C., G.S.C., A.H., K.F.S. and D.M. were responsible for the funding; S.H. and I.B. drafted the manuscript; and all authors critically revised the manuscript for important intellectual content and approved the final version.

Competing interests

All authors are involved in the development, update, implementation, and dissemination of numerous reporting guidelines and are members of the SPIRIT–CONSORT Working Group. S.H., I.B., A.-W.C., A.H., K.F.S. and D.M. are members of the SPIRIT–CONSORT Executive Group. G.S.C. is the director of the UK EQUATOR Centre, D.M. is the director of the Canadian EQUATOR Centre, and J.A.d.B. is affiliated with the UK EQUATOR Centre; these are all part of the EQUATOR Network, an organization that promotes reporting guidelines. I.B. is deputy director of the French EQUATOR Centre.