

## Using SPIRIT for peer review

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Have you been asked to peer review a protocol of a randomised controlled trial?

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SPIRIT can help make your job easier.

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In this video, we'll tell you what SPIRIT is,

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why peer reviewers find SPIRIT helpful,

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and how to use SPIRIT when peer reviewing randomised trial protocols.

### What SPIRIT is

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SPIRIT is a reporting guideline.

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Reporting guidelines are a list of minimum items that a person needs to fully understand a report of research.

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There are lots of reporting guidelines, each for a specific study type.

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SPIRIT is the reporting guideline for reporting the protocol for a randomised controlled trial.

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For other study designs that your journal publishes, visit the EQUATOR Network for help in finding appropriate reporting guidelines.

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The SPIRIT statement is a document with 34 items.

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In the actual checklist, each item is given a line or two of description.

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For example, item 4, trial registration, is “the name of trial registry, identifying number with URL, and date of registration;

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or, if the trial is not yet registered, the name of intended registry."

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These 34 items follow the structure of a trial protocol covering: 3 items of administrative information;

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five items on open science declarations;

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two items for the introduction;

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19 items for the methods;

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and five items related to ethics.

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So SPIRIT focuses much more on the methods - the things that the researchers plan to do - than anything else.

## **Why peer reviewers use SPIRIT**

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You might be thinking: if SPIRIT is guidance for *reporting* trial protocols, why would I use it when *reviewing* a trial protocol?

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As a peer reviewer, a big part of your job is to assess whether a trial is likely to produce results that are valid (or "true"), and clinically important.

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But trial protocols are often missing some of the information you need to completely judge whether their methods are robust and the information being collected is important.

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Authors have to keep in mind a lot of different information when they write their trial protocol.

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Very often they forget to mention at least one or two things.

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When you review a trial protocol, you might find you focus on evaluating the information that is *there*; it is easy to overlook that something important is *missing*.

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SPIRIT reminds you of all the details you need to check so that you can provide a complete review.

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It's a bit like when you go shopping. You might remember the 10 things you need...

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...but why not make your life easier by seeing them all written down?

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That way you spend less time trying to spot what the authors have forgotten to tell you,

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and more time reviewing what they are planning to do.

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SPIRIT was created by groups of people who work with clinical trials and their protocols, like trialists, statisticians, systematic reviewers,

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healthcare professionals, patients, and funders.

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Because trialists, statisticians, and systematic reviewers helped shape SPIRIT,

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the checklist items cover the critical details you'll need to be able to judge whether the trial is likely to produce valid results, or whether there is potential for bias.

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Because patients and healthcare professionals were involved,

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SPIRIT asks for the information you'll need to judge whether the questions the researchers are asking matter clinically.

## **How to use SPIRIT for peer review**

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How exactly can you use SPIRIT to help with your peer review?

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You could use SPIRIT to do an initial check for any information that is obviously missing.

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If there is information that SPIRIT asks for that the author has not provided, contact the journal to ask for the additional details.

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Some journals ask authors to submit a completed SPIRIT checklist along with their randomised trial protocol.

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Authors can write which page of the manuscript they have reported each item on.

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Check whether there is a completed checklist among the files you've been asked to review.

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This can help you find the relevant information quickly,

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but make sure the authors have really included the information that they say they have!

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And watch out for authors writing "Not Applicable" or "N/A."

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Authors sometimes say an item is not applicable and don't mention it in their protocol

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when they actually mean that they don't plan to do or to consider something.

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For example, if nobody in their trial will be blinded, they might note on the checklist that the items on blinding are not applicable.

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But actually, the fact that nobody will be blinded is important information.

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It doesn't automatically mean that the protocol is bad or that the journal should reject the manuscript - blinding is not always feasible. But you need to know that nobody in their trial will be blinded so that you can think about how that might affect the results of the trial.

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So if the authors don't mention a SPIRIT item explicitly, ask them to confirm in the manuscript what they plan to do or not to do.

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You - and people who read the trial protocol in the future - shouldn't have to assume or guess.

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You could use SPIRIT to remind you of important things to check when reviewing the protocol.

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For each checklist item, look at what the authors report that they will do.

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If there are weaknesses or problems in the methods that they plan to use, mention this in your review.

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Remember that SPIRIT is guidance for reporting, not for methods.

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For example, item 27 includes methods to handle missing data.

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There are different ways of dealing with missing data.

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Which methods are appropriate will depend on the specific trial and the type of data that might be missing.

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SPIRIT doesn't specify particular methods that are acceptable or not acceptable. It just reminds you to check what the authors plan to do.

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Then it's up to you to decide whether the methods they plan to use are appropriate for their trial.

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Finally, you could use SPIRIT before you submit your review to the journal. Do a final check to make sure you've considered all of the most important aspects of the study design.

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You might come across an item where you're not sure what SPIRIT means or why the item matters.

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The SPIRIT "Explanation and Elaboration" paper explains why each item is important and describes any nuance or challenges that you might like to think about.

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It also gives examples for reporting of each checklist item.

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This “E&E” document is really helpful as a reference to dip into when you need it. You can download it on our website.

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This is the end of this training video on what SPIRIT is,

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why peer reviewers find SPIRIT helpful, and how to use SPIRIT when peer reviewing randomised trial protocols.

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The 2025 update of SPIRIT and CONSORT was funded by the MRC and NIHR.

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Thank you for using SPIRIT when you peer review randomised trial protocols.

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By building a better evidence base today, we're ensuring better quality research in the future.