

How to use SPIRIT 2025 when writing a trial protocol

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You're ready to write the protocol for your trial.

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How can SPIRIT help make your job easier?

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

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why you might want to use it, and how to use it.

What SPIRIT is

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SPIRIT is reporting guideline.

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Reporting guidelines are a list of minimum items that a person needs to fully understand your trial.

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They tend to be given as checklists or as structured text listing the information.

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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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If you're working with other study designs, visit the EQUATOR Network for help in finding an appropriate reporting guideline.

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The SPIRIT Checklist includes 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; or, if the trial is not yet registered, the name of the 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 on the methods,

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and five items related to ethics.

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So SPIRIT focuses on the methods - what you're planning to do - more than anything else.

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There are two different types of trial protocol that you might write:

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an abridged trial protocol article that you might publish in a journal article, and the full trial protocol that you might use for ethics or regulatory approval.

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SPIRIT can be used as a guide for both types of protocol.

Why researchers use SPIRIT

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You might be wondering

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why you need this checklist. There's a few reasons why this checklist can be helpful.

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Planning a trial means making a lot of decisions about the trial design.

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Using SPIRIT when writing your protocol reminds you to think about all of these critical issues and report the decisions that you make.

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That means you can focus on making the right decisions for your trial.

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And making explicit decisions early in the planning process can help you to design and conduct a more robust trial.

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SPIRIT was created by groups of people who work with clinical trials and their protocols, like healthcare professionals, trialists, statisticians, patients and funders.

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So by using SPIRIT, you'll be including all the information that all of these different audiences need to use your protocol.

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A well designed and complete trial protocol will help with approvals by the trial funder, research efforts committee, and regulator.

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People will have the information they need to judge your trial on the first round of review, so you won't waste their time and yours. And you're also showing them that you know what is needed in the field - that you understand the standards.

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A well designed and complete protocol will also help with smooth and efficient trial conduct.

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A well designed trial runs more easily.

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Everyone involved knows what they need to do.

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Fewer amendments will be needed

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and there are less likely to be delays in approvals.

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Using SPIRIT for your protocol will also help you when you come to write up your trial results.

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CONSORT is the companion guideline for reporting trial results

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by using SPIRIT to write your protocol. When the time comes to write up your trial results, half the paper is planned out already.

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You have a lot of the information you need and the CONSORT also requires, so your results paper will be much easier to write.

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You can find out more about CONSORT on our website.

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SPIRIT will also help with peer review of that results paper.

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A more robust, well planned trial means easier peer review.

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SPIRIT does not tell you how to design your trial,

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but it does make you think about the important design choices, so you won't sleepwalk into bad design.

How to use SPIRIT when writing

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How exactly do you use SPIRIT? To help make writing your trial protocol easier,

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you could look at SPIRIT when you are planning your trial protocol.

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You could check what information you'll need and make sure you've got it;

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identify where you need to decide what methods to use;

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and you might need to contact other team members for some information or to discuss methods.

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Make sure everyone on their team has a copy of SPIRIT.

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You could use SPIRIT as a writing template to make an outline for the trial protocol.

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Start by adding main section headings like Introduction and Methods.

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Then add each item in SPIRIT as a sub-heading under the appropriate section.

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The example of the screen just shows a few of the SPIRIT headings.

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SPIRIT is a minimum list of essential items for writing a trial protocol.

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If there are more details that a reader needs about something that SPIRIT doesn't mention, add them in.

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If you're writing a trial protocol to submit to a journal for publication, check if the journal requires any additional sections, such as a brief discussion.

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You might come across an item where you're not sure what SPIRIT means, or you'd like to see an example of how to add that information.

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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 each checklist item. 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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Remember, readers should never have to assume what you did.

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If you use SPIRIT to help guide your writing, it is good practise to say so. In your methods section states that this protocol was reported following the SPIRIT reporting guideline and cite the version that you used.

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Be careful not to say that her trial will be conducted FOLLOWING a reporting guideline.

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These guidance documents just tell you what decisions to write about. They don't tell you what the right decision is each time.

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Always say reported.

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Citing SPIRIT shows your readers that you are following good research practises.

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It also helps to educate readers about reporting guidelines so that more people will use them.

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You can use SPIRIT to help you write both your full trial protocol and a shorter version of your trial protocol as a journal article.

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Publishing a shortened version of your trial protocol as a journal article gives you academic credit for your work,

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greater dissemination of the trial,

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and a more complete public record than the trial registry.

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If you're writing a shorter, abridged trial protocol to submit to a journal for publication, you might be worrying about how you fit all the important information into a standard journal article's word count.

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Start by getting all the information down in your full trial protocol.

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Then, when writing your abridged protocol article, use SPIRIT to remind you of the minimum items you need to cover.

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The abridged protocol article will be shorter, but you still need to include all of the SPIRIT checklist items. You can do this by combining items to shorten your writing.

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For instance,

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Item 21 asks for how the randomisation sequence will be created. We could say, “a statistician will generate the 1:1 randomization list using Stata 13.0”.

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Item 23 asks how randomization will be implemented. We could say, “when new participants join the trial, the pharmacist will dispense the active or placebo tablet according to the randomization list”.

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Item 22 asks how the sequence will be kept a secret to maintain blinding. We could add that the statistician and pharmacist will be “independent” of the trial team.

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And item 24 asks about blinding. We can state that, “participants, research nurses and outcome assessors will be blind to allocation group” and that, “the tablets will have identical colour, weight, taste and smell”.

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You can also use SPIRIT to do a last check of protocol once you're happy with the text. Sometimes when lots of people are writing a protocol together and making lots of changes, important information gets lost.

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Do a last check to make sure everything is there before you submit your trial protocol to the funder, research ethics committee, regulator, or journal. If you're submitting a trial protocol to a journal, also check if the journal asks you to submit a completed checklist alongside the manuscript.

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You can download an editable checklist on our website. Next to each item, write which page of the draft that information can be found on.

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We've covered five times that SPIRIT can be useful.

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

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Why SPIRIT is useful for authors, and how to use SPIRIT when writing.

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The 2025 update of SPIRIT and CONSORT was funded by the MRC-NIHR. Thank you for using the reporting guidelines like SPIRIT to make sure your protocol includes all the important information that readers need.

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