Reporting of randomised controlled trials

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In this short video, we'll focus on how randomised trials are reported.

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We'll talk about what we mean by reporting; we'll introduce tools called “reporting guidelines” and explain what they are;

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and we'll discuss why it's so important that researchers record their trials completely and transparently.

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What is reporting?

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A huge amount of time, effort and money goes into carrying out randomised controlled trials. It's important that people can ***use*** the information that the trial provides.

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Different groups of people might use the results of the trial: for example, other researchers; healthcare providers such as doctors, nurses and physiotherapists; patients; and people who make decisions on health care policy and funding.

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For these people to be able to use the result of the trial, they need to know exactly what the researchers did and what they found out.

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This is where ***reporting*** comes in.

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Researchers can report - or share - information about their trial by writing articles for the scientific journals, presenting at conferences; and posting summaries online.

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What are reporting guidelines?

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When researchers are writing about their trial, they need to remember to report all of the information that all of their different audiences need.

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This can be difficult, and they'll often forget to mention at least one or two things.

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That's why we've developed tools called "***reporting guidelines***".

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Reporting guidelines are a list of minimum items that somebody needs to fully understand a research study. They usually take the form of checklists.

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It's a bit like when you go shopping. When you have lots of things you need to remember, it's helpful to have a list so you don't forget anything.

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SPIRIT and CONSORT are checklists for researchers to use when they report randomised controlled trials.

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SPIRIT is a checklist for information that researchers should include in their trial protocol - that is, the plan written before the trial starts that describes what the researchers are going to do.

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And CONSORT is a checklist of information that they should include in reports written when the trial is completed and they want to share their results.

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You might be wondering, who decides what information is essential?

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SPIRIT and CONSORT were developed by people who work with clinical trials and their results, such as researchers who carry out trials, statisticians, health care providers, and patients. So they include all the information these different groups need to be able to ***use*** a report of the trial.

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Why does complete and transparent reporting matter?

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Complete and transparent reporting means that people who read the trial report have all the information they need to be able to do several important things:

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1. Decide whether to trust the results of the trial.

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Researchers have to make lots of decisions about how to design and carry out their trial.

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Some decisions are more likely than others to mean the trial gives trustworthy results.

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Check out our website for the top things to look for when you read a report of a trial and how they affect the trustworthiness of the trial.

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2. Decide whether the treatment should be included in standard healthcare programmes.

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Decisions about health policy tend to be based on the results of several trials.

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Policymakers need to understand the similarities and differences between the different trials, and all the details about exactly what the researchers found so they can make an overall decision.

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3. Decide whether taking the new treatment is likely to be a good choice for an individual patient.

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This involves knowing about the people who were included in the trial. Were they very similar to or different from this patient?

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For example, their age; sex; how mild or severe their health condition is?

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Patients and clinicians also need to know about possible side effects so they can weigh these up against the potential benefits of the treatment.

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And 4. understand how to give the new treatment to a patient.

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For example, for a drug, the healthcare provider needs to know the right dose; how many times a day the patient should take it; what time of day; whether to give it as a pill or a liquid or an injection.

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For other kinds of treatments, it can be even more complicated. For example, for a course of psychological therapy, we might want to know whether it was delivered online or in person; individually or in a group; who provided the course and what training they received;

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what exactly the course modules included; over how many sessions; and over what time.

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When researchers report all of the information that the SPIRIT and CONSORT reporting guidelines ask

for, it means that people can ***use*** trial reports, so all the time, money and effort spent on carrying out the trial isn't wasted.