

Randomized Control Trials (RCTs) 101

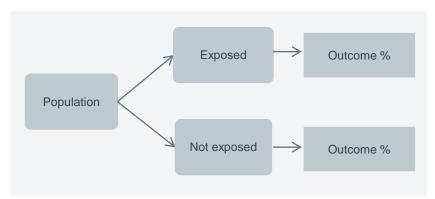
Educational Briefing

What is a randomized control trial?

- In a randomized control trial, participants are randomly divided into separate groups where one group is the experimental group (given a treatment or intervention) and the other group is the control group (not given the treatment or intervention). Then, researchers compare the two groups on a particular outcome.
- Unlike an observational studies, where researchers divide participants based on their particular attributes, randomized trials
 divide the participants by chance, which means the only expected difference between the groups should be the outcome variable
 being studied.

What is an example of an RCT?

• RCTs are commonly used for testing new pharmaceuticals. For instance, a company testing a new drug to determine whether it reduces the chance of having a heart attack might take a group of volunteers (the population) and randomly divide them into two groups. One group would take the new drug, while another group would take a placebo (such as an inactive sugar pill). Then, the researchers would follow them over a length of time and track whether the group taking the new drug had fewer heart attacks than the control group.



What are the most common types of RCTs?

While there is only one type of RCT, there are different types of study design that are often used.

- RCTs are often **blinded** or **masked**, which means that the groups that have been randomly selected don't know whether they are in the control group or the experimental group.
- The most rigorous RCTs are **double-blinded** or **double-masked**, which means that even the researchers conducting the blinded study don't know which participants are in the control group or the experimental group. This prevents bias because researchers might otherwise unconsciously treat some participants differently than others.

What type of causality can a RCT determine?

- There is significant debate over whether RCTs can determine causality (the idea that an intervention caused an outcome). However, most people agree that RCTs are the gold standard in providing evidence for causality.
- As with all studies, the ability to make causal inferences depends on the strength of the evidence, the similarity of the two groups being tested, and the outcome being studied.

How is this different than other study types?

- RCTs are generally seen as a stronger study design (and higher on the hierarchy of evidence) than observational studies (including cohort and case-control studies).
- When multiple RCTs are analyzed together in a meta-analysis or systematic review, they can provide strong evidence about the effectiveness of a treatment or efficacy of a drug, and they can help inform clinical guidelines.

Source: PubMed Health; Advisory Board insights and analysis.