

Exclusion Criteria

Exclusion criteria are characteristics that exclude people from taking part in a trial.

For example, depending on the requirements of the trial, exclusion criteria might include age, gender, type or stage of disease, and the presence or absence of other medical conditions. For a trial studying an anti-venom (snake bite) medicine, some of the criteria that would exclude an individual from taking part might be:

- Pregnancy
- Aged under 12 or over 70
- Previously received an anti-venom medicine
- Medical history includes wheezing, high blood pressure, heart disease
- Known adverse reaction to adrenaline.

Exclusion criteria (and inclusion criteria) are an important part of a trial protocol. If they are properly defined, exclusion and inclusion criteria will increase the chances of a trial producing reliable results. They also protect participants from harm and help avoid exploitation of vulnerable people (such as those unable to provide informed consent).

The reason for choosing the exclusion criteria should be documented with the trial protocol. Exclusion of certain groups can affect how realistic it is to generalise the trial results to the relevant patient population (external validity). This should be considered by researchers when they are designing a trial, and unnecessary exclusions should be avoided.