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Clinical trials are specialized medical research studies designed to determine if a healthcare intervention is effective compared to others, following research plans called protocols.

They also assess the safety of interventions and explore their effectiveness in specific settings or for particular groups of people.

## PHASES OF A CLINICAL TRIAL



Phase I

Healthy people

Phase II

People affected by the disease

Phase III

People affected by the disease

Adverse effects

Dosage

Possible harm

Efficacy
Adverse effects
Against a placebo

Efficacy over longer periods and in different countries

**10-15** years

## CLINICAL TRIAL LICENSING

a treatment is deemed safe by relevant national regulatory body

Phase IV: Safety Surveillance

Longer period of time
Different groups of people
Long-term adverse effects





In an RCT, participants are assigned to groups using special techniques.

Each person has the same statistical chance of being placed in any of the groups.

Simple random sequences can be generated by computers, or by old-fashioned methods like tossing a coin or picking a card from a shuffled deck.



One group of participants receives the intervention that is being investigated, while another group - the **control group**, receives a different intervention, or an inactive intervention (a placebo), or standard care.

The results from the groups are then compared.

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By comparing interventions in a controlled setting, RCTs offer insights about the **best outcomes** for patients.

Also, with their rigorous design RCTs can assess potential **risks** and benefits of new treatments before they are widely adopted in clinical practice.

RCTs are essential in healthcare due to their ability to provide high-quality evidence on treatment effectiveness.

## Want to know more?

- Check out <u>Cochrane Evidence Essentials</u>
- Read our reviews on <u>Cochrane Library</u>
- Follows us for being updated about EBM practice in the field of MS!

