Evidence stage

Quantitative experimental studies guide

Quantitative experimental studies

Randomised control trials (RCTs) are the most rigorous approach to generating evidence. RCTs are experiments which show an outcome has occurred as a result of the innovation that has been implemented. The simplest RCT would involve a group of people who are randomised into two separate groups. One of the groups is the ‘control’ group and the other are the ‘intervention’ group. The intervention group will use the innovation, but the control group will not or will use standard care.

Measuring outcomes, or changes, in both groups enables you to directly compare and determine if the innovation provides added benefits. As well as outcome measures related to the specific disease or clinical situation, you will need to measure whether there are any negative outcomes, side effects or harms.

Quality of life is also a useful outcome measure to include. This will help to establish how your innovation affects aspects of patients' daily living. You should involve patients or users of the intervention in the design of the research to ensure their views and preferences are taken into account. For example, they may suggest that certain outcome measures are particularly important to assess.

Designing the RCT and how it will be delivered requires a lot of planning. This will be key to the success of the experiment and the strength of the evidence that it generates.

Clinical trials are the most common type of RCT. If the RCT is being used to test new treatments such as medicines, procedures, devices or any other type of therapeutic intervention then it is a clinical trial. There are four phases of clinical trials:

Phase one

- test new treatments for the first time in humans
- small group of people
- evaluate dosage or intensity of the intervention and side effects or harms associated with its use

Phase two

- test treatments which have been shown to be safe in a phase one trial
- larger group of people

- monitor any adverse side effects

Phase three

- larger group of people from different regions or countries
- demonstrates safety and effectiveness
- confirm dosage or intensity
- identifies side effects
- measures the benefits and risks of the treatment
- where applicable, the new treatment is compared with existing treatments or the current standard of care

Phase four

- approved and licensed treatments
- monitoring the safety and effectiveness
- long-term risks and benefits
- identifying rare and long-term side effects

RCTs can take years to complete, but generating evidence through these studies is often an essential requirement for a therapeutic intervention to be adopted by the NHS. You can find out more on how to design, fund and deliver clinical trials from NIHR and NICE. It may be beneficial for you to seek advice from the outset around what the evidence requirements will be for your innovation. You can do that through registering with the NHS Innovation Service.

Other types of quantitative experimental studies include:

- non-randomised control trials
- before-and-after studies