The language of research (part 14): research methodologies: randomised controlled trials

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KEY WORDS
- Cause and effect
- Comparison
- Controlled
- Randomised
- Reliability
- Validity
- Variables

In the next three instalments of the Decoding Science series, we will explore randomised controlled trials (RCTs). To better understand why RCTs are considered so important in the armoury of research methodologies (*Box 1*) in medicine, some of the key features of RCTs will be discussed in this first paper. In the second paper, we will cover the terminology used in describing RCTs, and in the third and final paper in this miniseries, will describe how RCTs are undertaken.

KEY FEATURES

RCTs are considered, by many, to be the most important and useful research methodology to inform healthcare practice. RCTs are one of two research designs — the other being cohort studies — that are used to prove cause and effect (Ellis, 2016). RCTs are the most rigorous way of determining whether a cause–effect relation exists between treatment and outcome (Sibbald, 1998). RCTs are seen by many to be the 'gold standard of proof' when used to test the effectiveness and efficacy of medicines or other clinical intervention. There is a specific set of requirements and stages to complete when undertaking an RCT, and they may answer either one specific question or a group of closely interrelated questions. Most RCTs compare the use of medicines (or other healthcare interventions) with usual care or the standard at the time, and as such are used to prove the usefulness of a new approach to managing a disease or illness.

RCTs belong to a class of methodologies called experimental research or interventional study designs, which manipulate an intervention, rather than only observing and measuring. For example, honey (the intervention) is applied to a wound to measure its effect on healing, or silver is added to dressings (the intervention) to observe and measure its impact on the development of wound infections.

RCTs are used to explore the association between two, or sometimes more, variables, while other contributing factors are closely controlled to ensure the trial is both valid and reliable. To understand RCTs, it is important to understand the meaning of the terms variables, validity and reliability.

VARIABLES

RCTs are a research methodology to test cause and effect (exposure and outcome, respectively). RCTs, and interventional studies, seek to manipulate an exposure (the independent variable) in order to measure the effect it has on an outcome (the dependent variable) (Gordis, 2014). The independent variable is the variable under investigation, for example:
- Applying honey on a wound (the exposure or independent variable) to see its effect on wound healing (the outcome or dependent variable)
- Using silver in a dressing (the exposure or independent variable) to see its effect on infection rates (the outcome or dependent variable).

VALIDITY

Validity was discussed in some detail earlier in the Decoding Science series (Ellis, 2015a), but in brief, validity essentially refers to the proficiency

> **Box 1. Research methodology defined**
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> Methodologies are the broad approach to a research investigation that the researcher has chosen in order to investigate a topic or question of interest (Ellis, 2013). Different methodologies are used to address different research questions and, therefore, the choice of research methodology is an important aspect of planning research.

of a methodology (a study design) or a method (a data collection technique) to measure what it is designed to measure (Polit and Beck, 2008). For example, a calibrated and properly applied sphygmomanometer will measure a person's blood pressure with a fair degree of accuracy and validity. Other tools, such as questionnaires to measure patient satisfaction or pain, have a low validity.

RELIABILITY

Reliability measures the ability of an approach to get the same or similar result each time a study is repeated with a different population or group (Ellis, 2015b). The simplest form of reliability is inter-rater reliability. Inter-rater reliability is the reliability that two or more people will get the same result using the same intervention with the same method. For example, does a sphygmomanometer give the same reading (or similar) when used by the same nurse in the same patient in the same way at roughly the same time.

CONTROLLED

An RCT compares the outcomes of an experimental, interventional participant group with a 'control group'. The varible under investigation (the independent variable) is only tested in the intervention group, while the control group receives exactly the same care, and are treated in an identical manner apart from the intervention itself. They are often treated with 'usual care' or a placebo (more on this in the next paper in the series).

In a simple example, participants of the study arm are given antibiotics (the exposure/independent variable) to measure the effect they have on recovery time for a would infection (the outcome/dependent varible). The outcome is compared to the recovery time of participants in the control arm where the exposure/independent variable is a non-active copy of the antibiotic drug, a placebo. By comparing the length of recovery time between the two groups one can ascertain the likely impact of the antibiotics. If there was no control arm, and recovery from infection was observed in every patient on the antibiotic, it would be unknown whether the antibiotic had improved healing. Another example of the importance of a placebo is in the study of antibiotics in the healing time of viral colds. Antibiotics are known to have no effect against viruses, but without a placebo, one might observe recovery and conclude that the antibiotics caused or improved recovery.

PROSPECTIVE

A study that seeks to prove cause and effect should be undertaken in a prospective, real-time manner. It should not be retrospective, using old or existing data or relying on memory or recall.

This ensures that data are collected in the same way at the same time according to a pre-defined and agreed schedule, which means that unlike using old or archived data, researchers can manage the quality of the data using valid instruments applied in a consistent, reliable manner. Following a pre-defined procedure to collect prospective data is also useful when there are multiple centres or clinicians involved in collecting data.

CONCLUSION

This article has introduced the concept of the RCT and examined some of the main features that makes it one of the 'gold standards' of research methodology. The RCT as a research methodology is selected to show cause and effect, in a manner that is both valid and reliable. **Wuk**

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