# Understanding the quality of a quantitative paper (3): randomised controlled trials

KEY WORDS
- Blinding
- Methodology
- Randomised controlled trials (RCT)
- Research quality
- Quantitative

PETER ELLIS
*Independent Nursing and Health Care Consultant, Writer and Educator*

In the last paper in this series we continued to consider how one might assess the quality of quantitative research with reference to a randomised controlled trial (RCT; Ellis, 2022a). We considered the features of sampling and randomisation that researchers should explain and which tell the reader a lot about the applicability, generalisability, of the study to the sorts of people they care for. We saw how, as part of this requirement, the characteristics of the study sample need to be explained so that the healthcare professional can make this assessment.

We considered how randomisation is important in distributing the known and, more importantly, unknown characteristics of the study sample so that the two arms of the trial, cases and controls, are broadly similar at the start of the study. This makes any differences at the end of the study more likely to be due to the intervention than it is to sample selection biases.

In this paper we will consider the purpose of blinding, sometimes called masking, in RCTs, how this might be done and what its purpose is. As well as blinding, we will consider how a good RCT delivers interventions and trial-based care to the people in each arm of the study and why this happens.

## Bias

We said the main purpose of an RCT was to compare a medication, or intervention, with another so that the researchers can determine which is better (Ellis, 2022a), although in some circumstances there is more than one intervention. For simplicity, we will consider only the one. We said that people are entered into the intervention and control arm of the study in a random fashion, so that there is little chance of selection bias; where the researchers put certain people into an arm of a study because they fit the purposes of the study.

In research terms, bias is simply any factor within a study that may affect its findings (Parahoo, 2014), more simply thought of as factors that deviate the study from the truth.

As well as selection bias (Smith and Noble, 2014), a bias that can affect the RCT are related to how both study participants and researchers behave if they know which arm of the study participants are allocated to (Ellis, 2022b).

Behavioural biases are quite simply what they sound like, biases that affect the way in which people behave. In the case of RCTs this means for example, that if a participant knows they are receiving the active treatment, they behave differently to those participants in the other arm of the study. An example might be participants in a study of the role of exercise in promoting wound healing, those allocated to the exercise arm might increase the amount of exercise they do beyond that prescribed for the research because, consciously or not, they want the study to prove successful. Similarly, research staff who know which arm of a study a participant is allocated to might choose to spend more time on issues like smoking cessation with those allocated to the treatment because, like the participants, they too want the study to show a positive outcome. Such behaviours cause a deviation from the truth that the study is trying to determine.

The other bias that can occur if the researchers know which arm a participant is randomised to is observational bias. Polit and Beck (2014) identify that observation biases arises as a result of an observer's emotional prejudices, personal views or anticipation about what they might observe. In this sense, a researcher who is invested in a study, may see things in a different light when interacting with, or measuring outcomes among, different arms of the study. For example, in a study in that the outcome of interest is the rate of wound healing, a researcher may rate a wound in the treatment arm as having healed quicker than one on the control arm when in fact there is no difference.

It is important when reading an RCT that the researchers have identified and addressed these issues, so that the reader can make an appraisal about the quality of the research methodology and methods employed.

## Blinding

The main way in which the potential for observational and behavioural biases to

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be managed within an RCT is to blind the participants, and researchers, as to which arm of the study the individual participants are allocated to (Spieth et al, 2016). Blinding employs techniques to try to prevent the participants, researchers, or both, knowing which arm of a study a participant has been allocated to.

The first technique is the use of the placebo. A placebo is essentially a medication that looks like and is administered in the same way and frequency as an active medication, but is not active. This means that the participants taking the placebo don't get the active ingredient, but they get the same positive effect that taking a medication gives as well as being treated like the people in the intervention arm. A placebo in this case must be produced to look and feel, and taste if appropriate, like the real medication.

More frequently, people are given an existing medication for a condition that is compared in outcome to the research medication, in this case it is harder to blind the participants to what medication they are taking, other than by changing the labelling on the boxes which are used to dispense the medication.

In studies which involve an intervention, like counselling or a wound dressing, the alternative intervention is called a sham intervention, or as described above, the usual intervention is applied and compared with the intervention under research. Again the best papers describe how the placebo or sham intervention is derived and applied in detail so the reader can assess for themselves if they feel what has been done will control potential bias.

### Single and double-blind

Ideally, no-one involved in the research should know which arm of the study any participant is allocated to (Hariton and Locascio, 2018). This means both the researchers and the participants and kept in the dark about the allocation. Such strategies are called double-blind and are designed to ensure both participants and researchers behave in the same ways, regardless of allocation. It also reduces the potential for observer bias.

Where it is impossible to blind both researchers and participants, a single blind technique may be used (Parahoo, 2014). The best studies describe how the nature of the intervention is hidden, usually from the participant who, for example, may not be able to tell the difference between one wound dressing and another. In the best RCTs, this strategy is augmented by having the people doing the dressings being different to those collecting the data for the research, reducing observer bias. For example, if the study concerns the rate of wound healing, one person might remove the old dressing, clean the wound and withdraw while the researcher assesses the wound. The dressing is then undertaken without the researcher being present. The reader should be able to make their own assessment of how well the strategies employed to keep allocation secret are and therefore whether the outcomes of the study are going to be affected by bias.

### Equal treatment

In the blind scenario, it is also important participants in both arms of the study are treated in an identical way. The best studies should describe this as part of their study in the methods. For example, in a study comparing a new wound dressing to an existing wound dressing, both arms of the study should be subject to the same dressing regimes and practices, including number and spacing of treatments and be offered identical advice and support. The approach to measuring the rate of wound healing etc. should also be identical.

## CONCLUSION

A failure of a research paper describing an RCT to identify their strategies for managing blinding and the provision of identical regimens to participants in a study should ring alarm bells for any reader. Studies that don't control these forms of bias are often flawed and cannot be relied upon to provide the sorts of information needed to inform a change in practice.

There are alternative levels and methods that can be used to achieve blinding in RCTs, that must be described and critiqued to enable the reader to have a level of confidence in the execution of the study. Of course, in the real world, it is not always possible to achieve perfection in a study design, it is important that the researchers identify any compromises they make in the design of their study and what impact, if any, this might have on the quality of their research.