Blinding: an essential component in decreasing risk of bias in experimental designs

Dorothy Forbes

What is blinding?
Blinding (or masking) is the process used in experimental research by which study participants, persons caring for the participants, persons providing the intervention, data collectors and data analysts are kept unaware of group assignment (control vs intervention). Blinding aims to reduce the risk of bias that can be caused by an awareness of group assignment. With blinding, outcomes can be attributed to the intervention itself and not influenced by behaviour or assessment of outcomes that can result purely from knowledge of group allocation.

Why incorporate blinding?
Lack of blinding in randomised controlled trials (RCTs) has been shown to be associated with more exaggerated estimated intervention effects, by 9% on average. Studies with subjective outcomes are more likely to show these exaggerated estimates. In a systematic review of 250 RCTs, researchers observed a significant difference in the size of the estimated treatment effect between trials that reported ‘double-blinding’ compared with those that did not (p=0.01), with an overall OR 17% larger in active and placebo groups. However, blinding may not be possible in some studies where the intervention is obvious to the participants and/or persons administering the intervention (eg, an exercise intervention). Such studies can take other measures to reduce the risk of bias, such as treating participants according to a strict protocol to reduce the risk of differential behaviours by persons administering the intervention.

Blinding of outcome assessors is equally important to reduce the introduction of bias into the assessments and should be attempted whenever possible. Outcome assessments may be made by the participants themselves, by their healthcare providers, or by independent assessors. Blinding of the statistical analysis is achievable by simply labelling the participants’ data with non-identifying codes.

How to implement blinding?
Blinding is not a simple procedure. The researchers often need to engage a variety of approaches to enhance blinding. Boutron et al conducted a systematic review of methods used in pharmacological RCTs to establish blinding of patients and/or healthcare providers. These included providing treatments in identical form, specific methods to mask characteristics of the treatments (eg, added flavour or colour), or use of double dummy procedures and even simulation of an injection.

Methods to avoid unblinding involved use of active placebo, centralised assessment of side effects, and patients informed only in part about the potential side effects of each treatment. Some of the methods used for blinding outcome assessors included centralised assessment of complementary investigations, clinical examination that involved the use of video, audiotape or photography, and adjudication of clinical events. Clearly there are ethical considerations to blinding. All blinding approaches should be explained as part of the method and receive ethical approval from research ethics boards.

How to assess if blinding has been successful?
An attempt to blind participants and personnel does not always ensure successful blinding in practice. For example, for many blinded drug trials, the side effects of the drugs can reveal group allocation, unless the study compares two rather similar interventions (eg, drugs with similar side effects, or uses an active placebo). It has been suggested that it would be useful to ask trial participants at the end of the trial to guess which treatment they have received. And some reviews of such reports have been published. Evidence of correct guesses exceeding 50% would suggest that blinding may have been broken. However, responses may simply reflect the patients’ experiences in the trial. A good outcome will tend to be more often attributed to a placebo.

Risk of bias may be high for some outcomes and low for others. For example, knowledge of the assigned intervention may impact on behavioural outcomes (eg, number of visits to their physicians), while not impacting on physiological outcomes or mortality. Thus, assessments of risk of bias resulting from lack of blinding may need to be made separately for different
outcomes. Rather than assessing risk of bias for each outcome separately, it is often convenient to group outcomes with similar risks of bias. For example, there may be a common assessment for all subjective outcomes (eg, quality of life) that is different from objective outcomes (eg, blood work).

In summary, when considering the effectiveness of blinding in reducing the risk of bias, it is important to consider specifically:

1. Were the participants and study personnel blinded or not blinded?
2. Who assessed the outcomes and were they blinded or not blinded?
3. What was the risk of bias in the outcome assessment considering the subjectivity or objectivity of an outcome?

Competing interests None

References