

Blinding

The **internal validity** is assessed by adequacy of **allocation** sequence, concealment of **allocation** sequence, **blinding**, the balance of prognostic factors, **intent-to-treat** analysis, and completeness of follow-up. The reviewers need to have the ability to recognize the relationship between an explanatory factor and an **outcome** and to identify other variables (**confounding factors**) or **systematic error** (bias) that can distort the results. **Confounding factors** and study **bias** are different problems in the study that lead to an inaccurate estimate (underestimate or overestimate) of the true association between exposure and an outcome ¹⁾.

Is blinding used?

If there is blinding, who is blinded?

Has the blinding process been described?

Would it have been possible for the blinded person to realize which intervention was performed?

If no blinding is reported, can you think of a way in which blinding could have been done in the study (e.g., blinding the outcome assessor, etc.)?

Blinding or masking techniques seek to keep the information hidden from the patient and/or the physician. This prevents study patients and investigators from determining the group to which the individual has been assigned after allocation. Blinding cannot always be implemented but should always be considered whenever a study is being planned. The reviewer needs to validate whether the masking methods used were performed adequately. Hence, they have to verify not only if blinding techniques are used but also who was blinded and how it was conducted.

Patients may do better or worse, depending on the group to which they belong, based on their own desires or prior knowledge (placebo effect). If it is impossible to mask the patient or the principal physician, generally at least the evaluator is blinded during the outcome assessment to avoid interviewer bias. It is not prudent for the physician who is performing the investigation to be the same person who conducts the outcome assessment (evaluator). The physician who is treating the patient may have a special interest in going on with the research and unintentionally modify the information or influence the experimental group differently from the control group. This is even more important when the outcome is not objective.

¹⁾

Falavigna A, Blauth M, Kates SL. Critical review of a scientific manuscript: a practical guide for reviewers. J Neurosurg. 2018 Jan;128(1):312-321. doi: 10.3171/2017.5.JNS17809. Epub 2017 Oct 20. PubMed PMID: 29053077.

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