

Incorporating allocation concealment and blinding in randomized controlled trials

While we are happy to take credit for incorporating more information on blinding and concealment in our abstracts, the credit for stimulating us to do so belongs elsewhere. First, Ken Schulz and others have shown us that randomization, blinding, and concealment of allocation make a difference to the accuracy of trial reports. Second, Phillip Devereaux and others have taken us to task for failing to report these important features of clinical trials. Readers will find that abstracts of trials now include whether the randomization was concealed from those responsible for entering patients into trials and who was blinded to treatment allocation during the trial. This information will be provided under the “Design” heading in abstracts whenever it is possible to obtain it from the study report or, failing that, directly from the investigators.

Unfortunately, our experience to date shows that it is not always possible to acquire an unequivocal answer from authors about blinding or allocation concealment. For example, the trial may be billed as “double blind,” but the regimen appears to have adverse effects that might reveal to patients or investigators who was taking it; in such cases authors may not check to see if the blinding is maintained. Or the investigator indicates that sealed envelopes were used to conceal randomization, but whether the envelopes were opaque is not indicated. If, in our judgment, there is reason to suspect that blinding or concealment was not secure, we will indicate that by rating the appropriate feature as “unclear.” In doing so, we do not mean to offend investigators who have done their best to protect their trials from bias; rather, we wish to protect readers from us, the editors, conveying a sense of false security about studies for which we remain uncertain about the method used for concealment or blinding.

The definitions that we will use for the categories of allocation concealment are as follows:

Allocation concealed: The authors were deemed to have taken adequate measures to conceal allocation to study group assignments from those responsible for assessing patients for entry in the trial (e.g., central randomization; numbered, opaque, sealed envelopes; sealed envelopes from a closed bag; numbered or coded bottles or containers; drugs prepared by the pharmacy; or other descriptions that contain elements convincing of concealment).

Allocation not concealed: The authors were deemed not to have taken adequate measures to conceal allocation to study group assignments from those responsible for assessing patients for entry in the trial (e.g., no concealment procedure, sealed envelopes that were not opaque, or other descriptions that contain elements not convincing of concealment).

Unclear allocation concealment: The authors did not report or provide us with a description of an allocation concealment approach that allowed for classification as concealed or not concealed.

The definitions that we will use for the categories of blinding are as follows:

Blinded: Any or all of the clinicians, patients or participants, outcome assessors, or statisticians were unaware of who received which study intervention. If “initially” is indicated (e.g., blinded [patients and outcome assessor initially]), the code was broken during the trial, for instance, because of adverse effects.

Blinded (unclear): The authors did not report or provide us with an indication of who, if anyone, was unaware of who received which study intervention.

Unblinded: All participants in the trial (clinicians, patients or participants, outcome assessors, and statisticians) were aware of who received which study intervention.

These definitions have been added to the Glossary, which can be found in each issue of the journal.

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Editor