Double blind, you have been voted off the island!

“Double blind” is the term researchers frequently use, and readers frequently accept, as a key marker of the validity of a randomised controlled trial (RCT). Clinical trial experts and clinicians, when asked, are all ready to offer a definition of what double blind means. Unfortunately, however, their answers differ substantially. Thus, the term lacks consistency in its use and interpretation, a critical flaw for any technical term. In this editorial, we advocate abandoning the current blinding lexicon (ie, single, double, and triple blinding) and recommend transparent reporting of the blinding status of each group involved in the execution, monitoring, and reporting of clinical trials.

Blinding (or masking) in RCTs is the process of withholding information about treatment allocation from those who could potentially be influenced by this information. Blinding has long been considered an important safeguard against bias. Benjamin Franklin, in 1784, was probably the first to use blinding in scientific experimentation. Louis XVI commissioned Franklin to evaluate mesmerism, the most popular unconventional “healing fluid” of the eighteenth century. By applying a blinding fold to participants Franklin removed their knowledge of when mesmerism was and was not being applied. Blinding eliminated the intervention’s effects and established mesmerism as a sham. From this work, the scientific community recognised the power of blinding to enhance objectivity, and it quickly became, and remains, a commonly used strategy in scientific research.

The groups who can potentially introduce bias into an RCT through knowledge of the treatment allocation are shown in the table.

<table>
<thead>
<tr>
<th>Participants</th>
<th>Individuals who are randomly assigned to the interventions being evaluated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healthcare providers</td>
<td>The physicians, nurses, physiotherapists, or other personnel who care for the participants during the study period or administer the interventions</td>
</tr>
<tr>
<td>Data collectors</td>
<td>Individuals who collect data for the study outcomes. Data collection could include administering a questionnaire, taking a physical measurement, or eliciting symptoms</td>
</tr>
<tr>
<td>Judicial assessors of outcomes</td>
<td>The individuals who ultimately decide whether a participant has had the outcome, or outcomes, of interest</td>
</tr>
<tr>
<td>Data analysts</td>
<td>The individuals who conduct the data analysis</td>
</tr>
<tr>
<td>Data safety and monitoring committee</td>
<td>The committee that reviews the data to advise on the continuing safety of the trial and persistent uncertainty of the efficacy of the intervention being evaluated</td>
</tr>
<tr>
<td>Manuscript writers</td>
<td>The individuals who write versions of the manuscript before the breaking of the randomisation code: in a fully blinded study, one version is written with the assumption that group A received the experimental intervention, and the other is written with the assumption that group B received the experimental intervention</td>
</tr>
</tbody>
</table>

Groups that can potentially be blinded in RCTs

Although the true magnitude of bias introduced by unblinding remains (and is likely to remain) uncertain, clinicians should consider the blinding status of each group in assessing study validity. Unfortunately, suboptimal reporting of blinding status in full text publications and secondary journals has hindered readers’ ability to assess study validity. Authors have commonly relied on conventional blinding terminology (single, double, and triple blinding) to convey blinding status. We have shown great variability in physician interpretations and textbook definitions of these terms. It is for this reason that we recommend, and the editors of ACP Journal Club, Evidence-Based Medicine, Evidence-Based Mental Health, and Evidence-Based Nursing have adopted, a strategy of...
abandoning the current blinding terminology for transparent reporting of the blinding status of the groups listed in the table. As a result of this policy, readers will be able to make more informed decisions about the validity of the studies upon which they base their practice.

Although our editorial focuses on blinding in RCTs, the issue is also relevant for other study designs where knowledge of group membership may affect the results. For example, in cohort or case control studies where charts are abstracted by researchers to find outcomes or predisposing factors, readers should look to determine if the abstractors were blinded to group membership. Unblinded data abstractors may lead to variable recording of outcomes or predisposing factors. As in RCTs, blinding is not always possible. Notwithstanding the feasibility of blinding, readers should, when assessing the validity of a study, consider the blinding status of all groups who may introduce bias through knowledge of group membership.

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