

LETTERS TO THE EDITOR

ON THE INSUFFICIENCY OF REPORTING MASKING

Sir;

Villamar et al. (1) noted that masking was reported at a higher rate in 2010 than it was in 2000, but lamented that other aspects of CONSORT were not similarly improved. To place the reporting of masking in context, imagine a scenario in which the rehabilitation of patients with knee injuries was considered complete and successful as soon as these patients reported feeling better. Imagine a police department reporting lower crime rates on the basis of fewer among the accused reporting their guilt of the crimes of which they stand accused. These analogies are used not to discredit the reporting of masking; this is certainly part of the equation, necessary, but not in any way sufficient (2):

“The attempt to mask in no way equates to successful masking, and an uncorroborated statement with no test of the success of masking is simply not credible. Masking is not a binary phenomenon; it can be partially successful, and the extent to which it is successful determines the extent to which the trial is likely to be biased. The claim by itself does not ensure any level of success.”

One testable consequence of unmasking is blown allocation concealment (at least when restricted randomization is used, as it is in pretty much every randomized trial in practice) (3). This is why a test of the success of allocation concealment doubles also as a test of the success of masking (as opposed to just the attempt to mask, which is generally all that is meant when masking is reported), and must be a part of any serious evaluation of the success of masking. The Berger-Exner test of selection bias (4) is an objective test of the success of allocation concealment, and is subject to neither manipulation nor recall bias. The absence of any mention of this analysis means that we do not really know how successful the masking was in trials in 2000 or in 2010, and one can only hope that future trials do better.

Submitted November 21, 2012; accepted December 19, 2012

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RESPONSE TO THE LETTER TO THE EDITOR BY BERGER

As noted by Berger in his Letter to the Editor, different approaches may be used to provide valuable insights on randomized controlled trial (RCT) reporting or to objectively examine determinants of study quality. Among the latter he mentions the Berger-Exner test (4), which can assess the success of allocation concealment and detect selection bias in RCTs as factors that may influence the success of blinding.

Adequate randomization strategies and allocation concealment are critical aspects in order to maintain blinding and avoid bias in RCTs. However, the goal of our study was not centered on methods for systematically evaluating the success of their implementation. Rather, given the widespread use and acceptance of the CONSORT Statement among journal editors and clinical researchers, we chose to assess the extent to which authors abide to this minimum set of recommendations (5) when reporting blinding-related parameters in their RCTs, and whether any changes could be observed over time (1).

Although reporting of blinding is indeed not sufficient by itself to ensure trial validity, it is crucial in order to allow for critical appraisal of RCTs. Its complete absence or deficient reporting, as evidenced in many of the studies included in our review, is a serious flaw that hinders communication and interpretation of RCTs

in Physical Medicine and Rehabilitation (PM&R). Moreover, this finding suggests that the importance of blinding might not be fully acknowledged by authors, and even that blinding might be inadequate in a number of PM&R RCTs. The fact that no studies from 2000 or 2010 in our sample reported having tested for the success of blinding (1) may support this hypothesis. Therefore, in addition to an urgent need for improved reporting, the importance of more rigorous research in the field is further underscored. As a reasonable step towards this goal, future guidelines may consider inclusion of additional instruments that objectively evaluate determinants of study quality. Until then, stricter enforcement of current recommendations should be encouraged.

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