LETTER TO THE EDITOR

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.

REFERENCES

- Villamar MF, Contreras VS, Kuntz RE, Fregni F. The reporting of blinding in physical medicine and rehabilitation randomized controlled trials: A systematic review. J Rehabil Med 2013; 45: 6–13.
- 2. Berger VW. Conservative handling of missing information. J Clin Epidemiol 2012: 65: 1237–1238.
- Berger VW. Selection bias and covariate imbalances in randomized clinical trials. John Wiley & Sons: Chichester; 2005.
- Berger VW, Exner DV. Detecting selection bias in randomized clinical trials. Control Clin Trials 1999; 20: 319–327.
- Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. BMJ 2010; 340: c332.

Mauricio F. Villamar, MD^{1,2} and Felipe Fregni, MD, PhD, MPH¹*

From the ¹Laboratory of Neuromodulation, Department of Physical Medicine & Rehabilitation, Spaulding Rehabilitation Hospital and Massachusetts General Hospital, Harvard Medical School, Boston and ²School of Medicine, Pontifical Catholic University of Ecuador, Quito, Ecuador, Spaulding Rehabilitation Hospital, 125 Nashua Street #726, Boston, MA, USA 02114. *E-mail: Fregni.Felipe@mgh.harvard.edu