

LETTER TO EDITOR

Discrepancies between pre-specified and reported outcomes in your publication “Endovascular Revascularization and Supervised Exercise for Peripheral Artery Disease and Intermittent Claudication: A Randomized Clinical Trial “

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Dear Editor,

Your recent publication Fakhry *et al* reports outcomes that are different to those initially registered in the pre-trial protocol [1].

There was one pre-specified primary outcome at three time points reported correctly. However, there were 37 secondary outcomes of which 16 are not reported in the paper and 6 additional outcomes that were not pre-specified were reported without flagging these as such. Notably, the authors pre-specified 3 of the 8 components of the SF-36 as outcomes but reported only 2 of them. However, an additional 2 components of the SF-36 that were not pre-specified were reported.

JAMA has endorsed the CONSORT guidelines on best practice in trial reporting [2]. In order to reduce the risk of selective outcome reporting, CONSORT includes a commitment that all pre-specified primary and secondary outcomes should be reported; and that, where new outcomes are reported, it should be made clear that these were added at a later date, with an explanation of when and for what reason.

This letter has been sent as part of the COMPare project [3]. We aim to review all trials published from now in a sample of top journals, including JAMA. Where outcomes have been incorrectly reported we are writing letters to correct the record, and to audit the extent of this problem, in the hope that this will reduce its prevalence. We are maintaining a website at COMPare-Trials.org where we will be posting the submission date and publication date of this letter, alongside a summary of the data on each trial and journal. We hope that you will publish this letter so that those using the results of this trial to inform decision-making are aware of the discrepancies.

Yours faithfully,

Aaron Dale, Philip Hartley and Carl Henegan on behalf of the COMPare project team.

REFERENCES

- [1] Fakhry F, Spronk S, van der Laan L, et al. Endovascular Revascularization and Supervised Exercise for Peripheral Artery Disease and Intermittent Claudication: A Randomized Clinical Trial. *JAMA*. 2015;314(18):1936-1944.
- [2] Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *BMJ*. 2010;340:c869.
- [3] COMPare project website www.COMPare-Trials.org