

Dear Editor,

Your recent publication “Effects of Initiating Moderate Alcohol Intake on Cardiometabolic Risk in Adults With Type 2 Diabetes: A 2-Year Randomized, Controlled Trial” [1] reports outcomes that are different to those initially registered [2].

There was one pre-specified primary outcome, which was reported incorrectly as a secondary outcome in the main paper. In addition, the paper reports 5 “primary outcomes” that were not pre-specified, without flagging them as such. There was also 1 pre-specified secondary outcome, which is not reported anywhere in the publication. In addition, the paper reports 9 new secondary outcomes, which were not pre-specified, without flagging them as such.

Annals of Internal Medicine has endorsed the CONSORT guidelines [3] on best practice in trial reporting. 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 [4]. We aim to review all trials published from now in a sample of top journals, including Annals of Internal Medicine. 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 hope that you will publish our letter. Since this trial is now published and being used to inform decision making, and since this is a brief correction, on a matter of fact, from comparing two documents in the public domain, we also hope there will be no need for a lengthy review process or a publication delay awaiting an authors’ reply. 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.

Many thanks,

Eirion Slade, Henry Drysdale, Ben Goldacre on behalf of the COMPare project team.

[1] Gepner, Y., Golan, R., Harman-Boehm, I., Henkin, Y., Schwarzfuchs, D., Shelef, I., ... & Shai, I. (2015). Effects of Initiating Moderate Alcohol Intake on Cardiometabolic Risk in Adults With Type 2 Diabetes: A 2-Year Randomized, Controlled Trial. *Annals of Internal Medicine*, 163(8), 569-579.

[2] <https://clinicaltrials.gov/ct2/show/NCT00784433>

[3] Moher D et al, CONSORT 2010 Explanation and Elaboration: updated guidelines for reporting parallel group randomised trials, *BMJ* 2010; 340:c869.

[4] COMPare project website www.COMPare-Trials.org