

## LETTER TO THE EDITOR

### Registration of methodological studies, that is, “research-on-research” studies—should it be mandatory?



Editor

As authors of methodological studies, that is, studies also described as “research on research” or meta research, we often receive comments from editors and reviewers of our manuscripts, criticizing us for not having *a priori* registered or published study protocol. Such comments are sometimes accompanied by a reprimand that we are analyzing evidence, but that not having published study protocol is not in line with principles of evidence-based medicine.

Study registration has, so far, been required by International Committee of Medical Journal Editors (ICMJE) only for clinical trials. So far, there has been no comparable requirement for other types of studies, although it has been recommended that publishing protocols would be a good publication practice.

Trial registration has been required by ICMJE since 2005 because of growing concerns about lack of transparency and publication bias, as well as outcome reporting bias, in industry-sponsored trials. It was expected that such registration will push study sponsors to report all results that they were planning to do and prevent cherry-picking of results that will be published in a journal. It has emerged since then that registration is one thing and publication is another thing, with authors of many registered clinical trial protocols not publishing results years after being marked as completed. Furthermore, it has been reported that academia is doing much worse in this respect; in a recent study of Goldacre et al., trials with a commercial sponsor were substantially more likely to publish results compared with those with a noncommercial sponsor [1].

Publishing a systematic review (SR) protocol was suggested because of impact of SRs on clinical practice and clinical recommendations. Because SRs are considered the highest level in hierarchy of evidence in medicine, selectively reported and biased SRs may have a negative impact on clinical recommendations and practice, and it has been reported that publishing an SR protocol has multiple advantages [2].

However, it is unclear whether methodological studies (e.g., on the reporting/methodological quality of randomized controlled trials/SRs) should also be required to publish their protocol *a priori*. One advantage of such approach would be to avoid duplication of effort, as a registered protocol would inform other researchers that a certain study is already being conducted. Registered studies could also prompt potential collaborators to contact study authors, and someone could reach out to the author team to suggest improvements in study protocol. Publishing such protocol in a peer-reviewed journal has advantage of being peer-reviewed and findable in databases such as PubMed, which researchers usually search when conducting their own studies or finding information. However, protocol publication in peer-reviewed journals is associated with delays because of waiting for manuscript processing and peer review.

But, the question whether we should expect all methodological studies to have mandatory protocol publication is up for debate. It is expected that methodological studies will have implications for further research design and reporting, and thus indirect influence on human health. Any type of study should then be required to make the protocol publicly available before the start of the study.

Practical question of where to register a study then comes next. There are free-of-charge sources for posting research-related files, such as Open Science Framework [3]. For SRs, PROSPERO register was established [4], for example. There are also peer-reviewed journals that publish study protocols, but usually with a hefty price.

Until there is a consensus that protocols of methodological studies, or protocols of any studies, should be prospectively registered, editors and reviewers should not reprimand authors for not having their protocol published *a priori*.

Livia Puljak\*

Centre for Evidence-Based Medicine and Health Care  
Catholic University of Croatia  
Ilica 242, 10000 Zagreb, Croatia

Dawid Pieper

Institute for Research in Operative Medicine (IFOM)  
Witten/Herdecke University  
Ostmerheimer Str. 200, building 38  
51109 Cologne, Germany

Conflict of interest: None declared.

\*Corresponding author. Tel.: +385 1 370 66 00; fax: +385 1 370 66 01.

*E-mail addresses:* [livia.puljak@gmail.com](mailto:livia.puljak@gmail.com); [livia.puljak@uni-cath.hr](mailto:livia.puljak@uni-cath.hr) (L. Puljak)

## References

[1] Goldacre B, DeVito NJ, Heneghan C, Irving F, Bacon S, Fleminger J, et al. Compliance with requirement to report results on the EU

Clinical Trials Register: cohort study and web resource. *BMJ* 2018; 362:k3218.

[2] Allers K, Hoffmann F, Mathes T, Pieper D. Systematic reviews with published protocols compared to those without: more effort, older search. *J Clin Epidemiol* 2018;95:102–10.

[3] Open science framework. Available at <https://osf.io/>. Accessed July 20, 2019.

[4] PROSPERO. Available at <https://www.crd.york.ac.uk/prospéro/>. Accessed July 20, 2019.

<https://doi.org/10.1016/j.jclinepi.2019.06.017>