



Why there is a need to improve evaluation standards for clinical studies in orthopaedic and sports medicine

Robert Prill^{1,2} · Aleksandra Królikowska³ · Roland Becker^{1,2} · Jón Karlsson⁴

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Robust methods are required for patient evaluation in orthopaedics and sports medicine—now more than ever!

The time has passed when researchers performed studies on themselves or members of their families, such as when Wilhelm Conrad Roentgen was taking X-ray images of himself and his wife. Ethical approval is mandatory prior to every single study [3], which often causes significant difficulties in sufficiently answering burning clinical questions. Research reporting standards have been developed to improve the quality of clinical studies. Reporting guidelines and recommendations have been published, making research in a similar field more transparent, reproducible, and comparable with other studies. Well-known examples are the CONSORT checklist for randomized controlled trials and the STARD checklist for diagnostic accuracy studies [1, 7].

These checklists and reporting guidelines, along with other initiatives such as recommendations for the justification of new clinical studies through systematic reviews, are highlighting and trying to close research gaps and are attempting to avoid the production of research waste [4].

High-level systematic reviews help to draw sufficient conclusions based on the best available evidence [6]; however,

they can only be as good and conclusive as the studies from which they are synthesized.

Despite the general eagerness of authors to improve the quality of their studies, a recent paper highlighted the diversity in reporting clinical trials and the transparency in orthopaedics and sports medicine research practices [8]. The definition of the primary outcome and a clear presentation of the hypothesis for a study are essential at the end of its introduction, and the clinical importance of its findings should be emphasized.

The most common mistakes that could be easily avoided by authors include deficiencies in sample size calculation, which should ideally be based on results of previous or pilot studies. Randomization descriptions also need improvement, and commonly used phrases such as “patients randomly allocated to one group or the other” do not address the type of randomization or the allocation process. Greater attention is also required for control groups and the description of their intervention. The comparability of groups must somehow be ensured through specific inclusion and exclusion criteria, randomization, and a group allocation concept.

A lack of reporting of gender ratio, age, and disease status might also negatively influence the generalizability of results. Providing not only the information about the number of dropouts, but also the reason for dropouts, is mandatory, as is reporting the occurrence of any adverse events. Obviously, patient or examiner blinding in a clinical study is difficult in orthopaedics and sports medicine, but this issue may be partially solved by blinding the study’s statistician. For transparency of a study, especially regarding the methods and results, authors are strongly encouraged to pre-register their studies in official registers or at least in the Open Science Framework.

Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA) and Journal of Experimental Orthopaedics (JEO) offer strong support to both beginner and advanced researchers by organizing annual methodological courses concerning clinical studies and publishing, and, separately, systematic

✉ Robert Prill
Robert.Prill@mhb-fontane.de

¹ Center of Orthopaedics and Traumatology, University Hospital Brandenburg/Havel, Brandenburg Medical School Theodor Fontane, 14770 Brandenburg, Germany

² Faculty of Health Sciences Brandenburg, Department of Orthopaedics and Traumatology, Brandenburg Medical School Theodor Fontane, Hochstrasse 29, 14770 Brandenburg, Germany

³ Ergonomics and Biomedical Monitoring Laboratory, Department of Physiotherapy, Faculty of Health Sciences, Wrocław Medical University, 50-367 Wrocław, Poland

⁴ Department of Orthopaedics, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

reviews and meta-analysis. Furthermore, “A Basic Methods Handbook for Clinical Orthopaedic Research” has recently been published, providing essential knowledge in planning and conducting different types of studies in the best possible scientific manner [5].

Now, to leave no stone unturned and directly address research reporting standards, KSSTA strongly recommends that authors submit an appropriate checklist as an additional file according to their study design with sufficient information on the completeness of the study reporting. For some researchers, this seems logical and will already belong to common practice; for others, it might be confusing not knowing the appropriate checklist or reporting guidelines and the crucial aspects of designing a study. Therefore, it is highly recommended that the *EQUATOR Network* recommendations for reporting guidelines be followed [2]. The overall aim is to make a study’s design more transparent for authors, reviewers, editors, and—most importantly—the readers. Following this practice will also enhance the entire publishing process, and editors and reviewers can focus on improving manuscripts rather than on checking methods. For example, the CONSORT checklist is mandatory for a randomized controlled trial, referring precisely to each reported item in a manuscript. The most common checklists are available on the *Author’s Homepage*.

Finally, the readability and length of a manuscript are very important. While it is necessary to report the method of a study in a reproducible manner, it is unnecessary to write a long introduction. Since KSSTA is a specialist journal, general or well-known information is not needed. The authors should focus on the topic of their study from the very beginning of their manuscript. Reporting results in the text that are already shown in tables or graphs is redundant and

unnecessary. The report should be complete and interesting, but short and precise.

If these considerations are taken into account, manuscript publication will be very likely.

References

1. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig L et al (2015) STARD 2015: an updated list of essential items for reporting diagnostic accuracy studies. *BMJ* 351:h5527
2. EQUATOR Network (2022) Search for reporting guidelines, available at <https://www.equator-network.org/reporting-guidelines/>, accessed 15 July 2022
3. Jirout J (1974) The dynamic dependence of the lower cervical vertebrae on the atlanto-occipital joints. *Neuroradiology* 7:249–252
4. Kleinert S, Horton R (2014) How should medical science change? *The Lancet* 383:197–198
5. Musahl V, Karlsson J, Hirschmann MT, Ayeni OR, Marx RG, Koh JL et al (eds) (2019) Basic methods handbook for clinical orthopaedic research. Springer, Berlin, Heidelberg
6. Prill R, Karlsson J, Ayeni OR, Becker R (2021) Author guidelines for conducting systematic reviews and meta-analyses. *Knee Surg Sports Traumatol Arthrosc* 29:2739–2744
7. Schulz KF, Altman DG, Moher D (2010) CONSORT 2010 statement: updated guidelines for reporting parallel group randomised trials. *BMJ* 340:c332
8. Schulz R, Langen G, Prill R, Cassel M, Weissgerber TL (2022) Reporting and transparent research practices in sports medicine and orthopaedic clinical trials: a meta-research study. *BMJ Open* 12:e059347

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