

Publishing study protocols: Maximising research transparency and spotting spurious statistics.

Transparency is at the heart of research. We rely on authors to conduct research to a high standard, and report their findings in an honest and accountable manner. We publish studies that influence other surgeon's beliefs, and change care for individual patients. Through research, investigators have the potential to change the way that thousands of patients are treated, rather than just those in their operating theatre. Ensuring research quality, through transparent conduct and reporting, is critical to ensure optimal patient care and safety.

All too often research can be compromised by bias or error. One common example is selective reporting of results; when investigators report statistically significant findings and ignore other planned outcomes, sometimes even 'switching' to a more favorable primary outcome. This is a little like rolling a dice, and then changing the choice of number after seeing the lie of the dice.

The BJJ, along with many journals, have responded to the call for transparency by requiring submitted RCTs to be pre-registered on an official open access trial registration website (i.e. isrctn.com or clinicaltrials.gov). Registration should be completed before the first patient is recruited into the trial. This ensures that the investigators publicly announce the primary outcome tool and time-point prior to the analysis, to prevent the phenomena of switching.

The next step in ensuring transparency is the open access publication of the study protocol. Published protocols should include a detailed account of the planned study, and the proposed analyses. To ensure transparency, protocols must be submitted to the open access journal before the trial data collection is complete and prior to any analysis of the final dataset. While the protocol for a study may legitimately change during the study, for example due to changes in care pathways or in response to new evidence, it is not acceptable to change a protocol after data collection is complete. Any amendment to a protocol should be approved by the study oversight committees, including the Research Ethics Committee, and be carefully and openly documented. Appropriate methodological detail is important to ensure that at study completion, researchers follow the plan that they proposed, and analyse their findings according to the details of that plan. Deviation from the protocol must be explained to justify reasons for variation, allowing reviewers and readers to consider if this deviation may have unduly influenced the findings. For complex studies, greater detail should be given to the methods to allow others to interrogate and possibly replicate the approach. Best practice is to also publish statistical and health economic analysis plans in an open access journal.

The publication of protocols has other advantages, such as allowing clinicians exposure to studies many years before publication. This may reduce unnecessary duplication of research, or enable researchers to more closely align studies (i.e. harmonizing outcomes) to facilitate more meaningful future comparisons through evidence synthesis and meta-analysis.

Over the last 10 years there has been huge growth in high-quality research in trauma and orthopaedic surgery; involving both interventional and observational studies. Investigators have embraced the requirement to pre-register their

studies¹⁻⁴, and the most rigorously conducted studies published in the Bone and Joint Journal have formally published their protocol in an open access journal⁵⁻¹⁰. However, until recently the Bone and Joint Publishing Group have not had an avenue to facilitate the publication of such protocols.

Through the launch of Bone and Joint Open, we seek to maximize transparency, by publishing protocols, along with statistical and health economic analysis plans, for any type of research. We have recently published the first protocol and statistical analysis plan for randomised controlled trials (The FORCE Study and WHiTE 5 Trial^{11,12,13}), and the study protocol for a nationwide observational study (The British Orthopaedic Surgery Surveillance Study^{14,15}). In addition, Bone and Joint Open is an ideal platform to publish related feasibility work that forms the building blocks of funded research^{16,17}.

The journal keenly supports the growing research quality, and collaborative study efforts within trauma and orthopedic surgery. To achieve this, the Bone and Joint Publishing Group will provide an avenue to publish work that maximises research transparency for the benefit of surgeons and patients.

References

1. **Fillingham YA, Darrith B, Calkins TE, Abdel MP, Malkani AL, Schwarzkopf R, et al.** 2019 Mark Coventry Award: A multicentre randomized clinical trial of tranexamic acid in revision total knee arthroplasty: does the dosing regimen matter? *The Bone & Joint Journal* 2019;101-B(7_Supple_C):10-16.
2. **Yang J, Parvizi J, Hansen EN, Culvern CN, Segreti JC, Tan T, et al.** 2020 Mark Coventry Award: Microorganism-directed oral antibiotics reduce the rate of failure due to further infection after two-stage revision hip or knee arthroplasty for chronic infection: a multicentre randomized controlled trial at a minimum of two years. *The Bone & Joint Journal* 2020;102-B(6_Supple_A):3-9.
3. **Hull PD, Chou DTS, Lewis S, Carrothers AD, Queally JM, Allison A, et al.** Knee Fix or Replace Trial (KFORT): a randomized controlled feasibility study. *The Bone & Joint Journal* 2019;101-B(11):1408-1415.
4. **Ueyama H, Kanemoto N, Minoda Y, Taniguchi Y, Nakamura H.** 2020 Chitranjan S. Ranawat Award: Perioperative essential amino acid supplementation suppresses rectus femoris muscle atrophy and accelerates early functional recovery following total knee arthroplasty: a prospective double-blind randomized controlled trial. *The Bone & Joint Journal* 2020;102-B(6_Supple_A):10-18.
5. **Leo DG, Jones H, Murphy R, Leong JW, Gambling T, Long AF, et al.** The outcomes of Perthes' disease: Development of a core outcomes set for clinical trials in Perthes' disease. *The Bone & Joint Journal* 2020;102-B(5):611-617.

6. **Joseph MN, Achten J, Parsons NR, Costa ML, On behalf of the PAT Trial Collaborators.** The PAT randomized clinical trial: total knee arthroplasty versus patellofemoral arthroplasty in patients with severe arthritis of the patellofemoral joint. *The Bone & Joint Journal* 2020;102-B(3):310–318.
7. **Gwilym S, Sansom L, Rombach I, Dutton SJ, Achten J, Costa ML.** Woodcast versus standard casting material for the immobilization of nonoperatively treated distal radial fractures: a randomized parallel-group feasibility trial. *The Bone & Joint Journal* 2020;102-B(1):48–54.
8. **Petrou S, Parker B, Masters J, Achten J, Bruce J, Lamb SE, et al.** Cost-effectiveness of negative-pressure wound therapy in adults with severe open fractures of the lower limb: evidence from the WOLLF randomized controlled trial. *The Bone & Joint Journal* 2019;101-B(11):1392–1401.
9. **Cehic M, Lerner RG, Achten J, Griffin XL, Prieto-Alhambra D, Costa ML.** Prescribing and adherence to bone protection medications following hip fracture in the United Kingdom: results from the World Hip Trauma Evaluation (WHiTE) cohort study. *The Bone & Joint Journal* 2019;101-B(11):1402–1407.
10. **Costa ML, Achten J, Rangan A, Lamb SE, Parsons NR.** Percutaneous fixation with Kirschner wires versus volar locking-plate fixation in adults with dorsally displaced fracture of distal radius: five-year follow-up of a randomized controlled trial. *The Bone & Joint Journal* 2019;101-B(8):978–983.
11. **Achten J, Knight R, Dutton SJ, Costa ML, Mason J, Dritsaki M, et al.** A multicentre prospective randomized equivalence trial of a soft bandage and immediate discharge versus current treatment with rigid immobilization for torus fractures of the distal radius in children: protocol for the Forearm Fracture Recovery in Children Evaluation (FORCE) trial. *Bone & Joint Open* 2020;1(6):214–221.
12. **Knight R, Dritsaki M, Mason J, Perry DC, Dutton SJ.** The Forearm Fracture Recovery in Children Evaluation (FORCE) trial: statistical and health economic analysis plan for an equivalence randomized controlled trial of treatment for torus fractures of the distal radius in children. *Bone & Joint Open* 2020;1(6):205–213.
13. **Png ME, Fernandez MA, Achten J, Parsons N, McGibbon A, Gould J, et al.** Economic evaluation plan of a RCT of hydroxyapatite-coated uncemented hemiarthroplasty versus cemented hemiarthroplasty for the treatment of displaced intracapsular hip fractures: the WHiTE5 trial. *Bone & Joint Open* 2020;1(3):8–13.
14. **Perry DC, Arch B, Appelbe D, Francis P, Spowart C, Knight M.** The BOSS Study. Determining the incidence and clinical outcomes of uncommon conditions and events in orthopaedic surgery. *Bone & Joint Open* 2020;1(3):41–46.

15. **Perry DC, Arch B, Appelbe D, Francis P, Spowart C, Knight M.** A protocol for a nationwide multicentre, prospective surveillance cohort and nested-consented cohort to determine the incidence and clinical outcomes of slipped capital femoral epiphysis. *Bone & Joint Open* 2020;1(3):35–40.
16. **Widnall J, Capstick T, Wijesekera M, Messahel S, Perry DC.** Pain scores in torus fractures: Using text messages as an outcome collection tool. *Bone & Joint Open* 2020;1(2):3–7.
17. **Marson BA, Craxford S, Deshmukh SR, Grindlay D, Manning J, Ollivere BJ.** Outcomes reported in trials of childhood fractures: a systematic review. *Bone & Joint Open* 2020;1(5):167–174.