



EDITOR'S PAGE

Trial registration: a pre-requisite for publication and an ethical responsibility

LA Harvey

Sydney, Australia

E-mail: lisa.harvey@sydney.edu.au

Spinal Cord already requires trials to be registered however currently retrospective registration is acceptable. This will change for any trial that commences after the 1st January 2018. These trials must be prospectively registered to be published in *Spinal Cord*. This move will bring *Spinal Cord* in line with all other large medical journals and most rehabilitation journals.

What is a trial? A trial is 'any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Medical interventions include any intervention used to modify a health outcome and include drugs, surgical procedures, devices, behavioural treatments, etc'.¹ This includes randomised controlled trials, pre-post studies, cross-over studies and alike. It also includes studies which do not have control groups and do not involve randomisation.

How do I register my trial? There are many different trial registries across different countries. The most commonly-used ones are www.clinicaltrials.gov and www.who.int/ictrp/en. Trial registration is usually free of charge. Authors merely need to submit a form which outlines the protocol and intention of their trial. Importantly, this process needs to be completed before recruitment of the first participant.

Why is trial registration important? Trial registration is important for minimising bias. Bias tends to exaggerate treatment effectiveness which in turn gives a distorted impression of scientific truth. There are many different sources and types of bias but two important ones addressed by trial registration are publication bias and reporting bias.

How does trial registration help reduce publication bias? Publication bias refers to the preferential publication of trials with positive findings. Publication bias is particularly common with small trials because large trials tend to be published regardless of results but small trials are unlikely to be published unless the results are positive. This gives a distorted picture of the real situation because readers only see half the trials on a topic and consequently only see half the truth. Publication bias is particularly problematic for spinal cord injuries where most trials are small. Trial registration helps overcome publication bias because it flags the existence of all trials. This helps raise questions about the results of trials never published.

How does trial registration help reduce reporting bias? Trial registration helps reduce reporting bias that arises when authors selectively report the positive outcomes of a trial without declaring the existence of negative outcomes. Alternatively, the hierarchy of outcomes are shuffled upon completion of a trial to give outcomes with positive findings the status of primary outcome. Trial registration helps overcome these problems because authors are required to articulate all outcomes and identify their primary outcome/s before knowing the results of the trial.

What if I have already started my trial but did not register it? If you have already started your trial and did not register it, then you should register it now. *Spinal Cord* will allow retrospective trial registration for all trials that started before 1st January 2018.

Will this policy direct unregistered but potentially good papers to other journals and thereby compromise Spinal Cord? It is unlikely that this will happen because most rehabilitation and high quality journals are now enforcing the same policy. For example, Archives of Physical Medicine and Rehabilitation² recently led a campaign requesting all rehabilitation journal editors to commit to this policy. Trial registration is also a requirement for membership of journals to the International Committee of Medical Journal Editors and is insisted upon within the Declaration of Helsinki. Importantly, if all journals adopt this policy then authors will get a consistent message and will not be tempted to shop around for a journal that has lower standards. All journals have a shared responsibility to enforce the same policy for the overall goal of reducing bias in research.³

Why is this an ethical issue? We all have an ethical responsibility to ensure research is truthful and free of bias.⁴ Trial registration helps achieve this and is therefore not a choice but an ethical responsibility for journals and researchers.

1 World Health Organisation. Clinical trials. http://www.who.int/topics/clinical_trials/en/. Accessed on 21st Feb 2017.
2 Chan L, Heinemann AW. Clinical Trial Registration: The Time Has Come. *Arch Phys Med Rehabil* 2015; **96**: 2093.

- 3 Wager E, Williams P, OPEN (Overcome failure to Publish nEgative fiNDings) Project Consortium. 'Hardly worth the effort'? Medical journals' policies and their editors' and publishers' views on trial registration and publication bias: quantitative and qualitative study. *BMJ* 2013; **347**: f5248.
- 4 Wade D. Registration of all rehabilitation clinical trials: an ethical and editorial imperative. *Clin Rehabil* 2016; **30**: 211–212.

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