



Minerva Access is the Institutional Repository of The University of Melbourne

Author/s:

Gray, R;Brown, E;Gray, G

Title:

A review of prospective trial registration in the Journal of Advanced Nursing in 2018

Date:

2019-10-01

Citation:

Gray, R., Brown, E. & Gray, G. (2019). A review of prospective trial registration in the Journal of Advanced Nursing in 2018. *Journal of Advanced Nursing*, 75 (10), pp.2051-2053. <https://doi.org/10.1111/jan.14090>.

Persistent Link:

<https://hdl.handle.net/11343/286133>

EDITORIAL

A review of prospective trial registration in the Journal of Advanced Nursing in 2018

Richard Gray¹ Ellie Brown^{2,3} and George Gray⁴

1. School of Nursing and Midwifery, La Trobe University, Melbourne, Australia
2. Orygen, The National Centre of Excellence in Youth Mental Health, 35 Poplar Road, Parkville, Melbourne, Australia
3. Centre for Youth Mental Health, the University of Melbourne, Melbourne, Australia
4. The Open University, Milton Keynes, UK

This is the author manuscript accepted for publication and has undergone full peer review but has not been through the copyediting, typesetting, pagination and proofreading process, which may lead to differences between this version and the [Version of Record](#). Please cite this article as [doi: 10.1111/JAN.14090](https://doi.org/10.1111/JAN.14090)

This article is protected by copyright. All rights reserved

PROFESSOR RICHARD JOHN GRAY (Orcid ID : 0000-0001-9694-4206)

Article type : Editorial

Corresponding author mail id: r.gray@latrobe.edu.au

EDITORIAL

A review of prospective trial registration in the Journal of Advanced Nursing in 2018

1. BACKGROUND

Registration creates a public record of planned clinical trials and is perhaps that most important weapon in ensuring unbiased reporting of clinical research. It is argued that registration reduces publication bias, the phenomenon where more positive or favourable findings are generally more likely to get published (Hunter, Seidler, & Askie, 2018). Outcome selection bias – where the researcher switches the outcomes of a study or only selectively reports favourable measures – may also be prevented by prospective trial registration. The World Health Organisation has a list of trial registries that meet specific criteria (<https://www.who.int/ictrp/network/primary/en/>) that include content, quality and validity, and accessibility.

Trials registration should be completed prospectively, that is to say, before the first participants is enrolled in the study. If a trial is registered after the first enrolment, it is defined as being retrospectively registered. Delayed registration negates the key benefits of registration and, it has been argued, has little scientific merit.

The *Journal of Advanced Nursing* author guidelines state that clinical trials are to be “prospectively registered” in a publicly accessible database. However, the editors then walk

this back slightly by stating that authors need to give reasons if a trial was not registered or was retrospectively registered. In a *Journal of Advanced Nursing* editorial (Noyes, 2018) reiterates the need for prospective registration – which she argues is optimal but concludes that "retrospective registration is possible to enable publication."

Authors of a recent analysis of trial registration trends in 9,450 trials registered on the Australian and New Zealand Clinical Trial Registry (ANZCTR) - a widely used WHO listed registry - found an increase in prospective registration, from 48% in 2005 to 63% in 2012 (Hunter et al., 2018). Subsequently, plateauing at around 64%. Gray, Badnapurkar, & Thomas (2016) reviewed the registration status of 44 trials published in the *Journal of Advanced Nursing* over five years from 2011 and 2016, six (14%) were prospectively registered.

2. METHOD

This review aimed to determine the number of randomized controlled trials published in the *Journal of Advanced Nursing* in 2018 that were prospectively registered. Trials were identified by manually searching the title and abstract of papers published in volume 74 (issues 1 through 12) and listed on the journal website (accepted and in-press papers were excluded). Using trial registration definitions used by Gray et al (2017) we coded included trials as 1. prospectively registered, 2. retrospectively registered, 3. not registered (including trials that were registered but this was not reported in the manuscript). We also extracted information about the reporting of the registration number as part of the abstract, the inclusion of study design in the title, trial design (e.g. pilot/feasibility, full trial), sample size and the country where the fieldwork was undertaken. From trials that were retrospectively or not registered we also extracted the reasons for this reported in the manuscript.

3. RESULTS

According to SCOPUS the *Journal of Advanced Nursing* published 288 documents (of which we coded 148 reporting primary research) in 2018. Our search identified six (4% of research papers) randomised controlled trials that were included in this review (Chiu et al., 2018; Daigle, Talbot, & French, 2018; Sampaio, Araújo, Sequeira, Canut, & Martins, 2018; Strandell-Laine et al., 2018; Wang et al., 2018; Zhu et al., 2018). Two trials were registered with clinicaltrials.gov, two with ISRCTN (International Standard Randomised Controlled

Trials Number) and one with the Chinese clinical trials registry. Dates when fieldwork was conducted were reported in 5 (83%) papers. Most authors (n=5, 83%) reported an evaluation of some type of psychosocial intervention (e.g. psychoeducation, education, mindfulness). Fieldwork for included trials was conducted in Asia (n=3, 50%), Europe (n=2, 33%) and North America (n=1, 17%). Most (n=5, 83%) papers did not specify the type of trial they were reporting; most seemed to be full trials testing specific hypotheses. One author stated they were reporting a pilot study. Mean sample size was 100 (SD=35.8, range= 62-162). The majority of trials were externally funded (n=5, 83%). Only one trial did not include a CONSORT diagram (Daigle et al., 2018).

Half of the included studies (n=3, 50%) were prospectively registered (Chiu et al., 2018; Sampaio et al., 2018; Wang et al., 2018). Two (33%) were retrospectively registered (Strandell-Laine et al., 2018; Zhu et al., 2018). One study was not registered (we emailed the author to confirm this) (Daigle et al., 2018). The authors of the retrospectively registered and unregistered trials did not provide any rationale for not prospectively registering their research. In the majority of papers (n=4, 67%) the registration number was reported as part of the abstract. In only one paper was the registration status of the trial reported as prospective in the manuscript (Sampaio et al., 2018).

4. DISCUSSION

This review aimed to determine the number of prospectively registered randomized controlled trials published in the *Journal of Advanced Nursing* in 2018. Half of the trials published were prospectively registered. Our observation provides evidence of improved rates of prospective trial registration in the *Journal of Advanced Nursing* given that between 2011 and 2016 only 14% were prospectively registered (Gray et al., 2016).

There is scope for authors, editors, and reviewers contributing to the *Journal of Advanced Nursing* to improve trial reporting. For example: Ensuring that registration numbers are reported as part of the abstract, providing a detailed justification why trials were not prospectively registered and ensuring authors noted in the title of the article that they are reporting a clinical trial.

We note that the *Journal of Advanced Nursing* editorial team could decide not to publish retrospectively registered trials. This – in our opinion – would likely be a poor strategic decision, risking non-publication of relevant trial data.

Whilst not convention, it may be informative to state in the abstract (alongside the registration number) the registration status of the trial (e.g. this trial was prospectively registered). This would inform the reader of the registration status of the manuscript; currently they are required to check the status on the registry.

A somewhat tangential discussion point, but a comment feels necessary. The pilot study reported by Daigle et al., (2018) was the only unregistered trial. Typically, pilot studies are an initial attempt by authors to test the feasibility study design – ahead of a full trial – and are not intended to test specific hypotheses (Leon, Davis, & Kraemer, 2011). Daigle et al., (2018) seemingly do hypothesis test, for example, stating that "MBSR [Mindfulness based stress reduction] produced significant improvements in distress."

In this review, we have examined only a small number of trials published in a single (high ranking) journal. We do not consider our findings generalizable (to nursing science journals); however, our observations are consistent with studies that report much lower rates of prospective trial registration in nursing, compared to biomedical science more generally (Gray et al., 2017; Hunter et al., 2018). We did not include non-randomised trials in this review and it is important to note that these studies – that meet standard definitions of a clinical trial – are not exempt from registration.

5. CONCLUSION

Rates of prospective trial registration are improving in the *Journal of Advanced Nursing*. However, there remains scope for further enhancement in reporting, notably ensuring authors of retrospectively registered trials provide a transparent rationale as to why their study was not registered.

REFERENCES

Chiu, H.-L., Chan, P.-T., Kao, C.-C., Chu, H., Chang, P.-C., Hsiao, S.-T. S., ... Chou, K.-R. (2018). Effectiveness of executive function training on mental set shifting, working memory

- and inhibition in healthy older adults: A double-blind randomized controlled trials. *Journal of Advanced Nursing*, 74(5), 1099–1113. <https://doi.org/10.1111/jan.13519>
- Daigle, S., Talbot, F., & French, D. J. (2018). Mindfulness-based stress reduction training yields improvements in well-being and rates of perceived nursing errors among hospital nurses. *Journal of Advanced Nursing*, 74(10), 2427–2430. <https://doi.org/10.1111/jan.13729>
- Gray, R., Badnapurkar, A., Hassanein, E., Thomas, D., Barguir, L., Baker, C., ... Topping, A. (2017). Registration of randomized controlled trials in nursing journals. *Research Integrity and Peer Review*, 2(1), 8. <https://doi.org/10.1186/s41073-017-0036-9>
- Gray, R., Badnapurkar, A., & Thomas, D. (2016). Reporting of clinical trials in nursing journals: how are we doing? *Journal of Advanced Nursing*. <https://doi.org/10.1111/jan.13149>
- Hunter, K. E., Seidler, A. L., & Askie, L. M. (2018). Prospective registration trends, reasons for retrospective registration and mechanisms to increase prospective registration compliance: descriptive analysis and survey. *BMJ Open*, 8(3), e019983. <https://doi.org/10.1136/bmjopen-2017-019983>
- Leon, A. C., Davis, L. L., & Kraemer, H. C. (2011). The Role and Interpretation of Pilot Studies in Clinical Research. *Journal of Psychiatric Research*, 45(5), 626–629. <https://doi.org/10.1016/j.jpsychires.2010.10.008>
- Noyes, J. (2018). Which studies should be registered on a clinical trials registry? *Journal of Advanced Nursing*, 74(11), 2479–2479. <https://doi.org/10.1111/jan.13696>
- Sampaio, F. M. C., Araújo, O., Sequeira, C., Canut, M. T. L., & Martins, T. (2018). A randomized controlled trial of a nursing psychotherapeutic intervention for anxiety in adult psychiatric outpatients. *Journal of Advanced Nursing*, 74(5), 1114–1126. <https://doi.org/10.1111/jan.13520>
- Strandell-Laine, C., Saarikoski, M., Löyttyniemi, E., Meretoja, R., Salminen, L., & Leino-Kilpi, H. (2018). Effectiveness of mobile cooperation intervention on students' clinical learning outcomes: A randomized controlled trial. *Journal of Advanced Nursing*, 74(6), 1319–1331. <https://doi.org/10.1111/jan.13542>
- Uniform requirements for manuscripts submitted to biomedical journals: Writing and editing for biomedical publication. (2010). *Journal of Pharmacology & Pharmacotherapeutics*, 1(1), 42–58.

Wang, W., Lim, J. Y., Lopez, V., Wu, V. X., Lee, C.-H., He, H.-G., & Jiang, Y. (2018). The effect of a self-help psychoeducation programme for people with coronary heart disease: A randomized controlled trial. *Journal of Advanced Nursing*, *74*(10), 2416–2426.

<https://doi.org/10.1111/jan.13793>

Zhu, L., Chan, W.-C. S., Liam, J. L. W., Xiao, C., Lim, E. C. C., Luo, N., ... He, H.-G. (2018). Effects of postoperative pain management educational interventions on the outcomes of parents and their children who underwent an inpatient elective surgery: A randomized controlled trial. *Journal of Advanced Nursing*, *74*(7), 1517–1530. <https://doi.org/10.1111/jan.13573>

Author Manuscript