

Transparency in the reporting of nursing research

Smith G, Gelling L, Haigh C, Barnason S, Allan H, Penny K & Jackson D

Recently, the integrity of reporting nursing research studies has been brought into question, with claims that less than half of clinical trials published in leading nursing journals are officially registered (Gray et al 2017). These authors suggest that because of this, the quality of published outcome analysis definitions and trial registrations in nursing journals is often sub-optimal.

At the *Journal of Clinical Nursing* we believe that all nursing research should be conducted with integrity, and in compliance with internationally recognized and accepted reporting guidelines. The end consumer of published nursing research will benefit by reading papers that clearly and transparently state how the study was conducted. Whether the reader is a clinical nurse who is seeking evidence to provide better care for patients or a student nurse trying to enhance their understanding of a specific topic, the benefits of responsible research reporting are considerable. Good quality nursing research which is reported responsibly has the potential to improve patient care, influence policy and to advance the nursing scientific knowledge base.

More than just endorsing reporting guidelines for our authors, we feel that is timely and important for our reviewers to be aware and comply with them. In summary, we believe that greater attention to proper trial registration and outcome analysis definition in published reports is imperative to, helping to ensure that good quality nursing care can be delivered from a valid and reliable evidence base.

Researchers often appeal to potential subjects' willingness to contribute to advancing science through study participation. Clinical trial registration is a means to assure and meet the ethical obligation to respect subjects' participation in research studies. (Krljeza-Jeric et al., 2005) Furthermore, accurately reported information from well-designed and rigorously conducted studies is necessary for readers to have confidence in the findings of research (Altman & Simera 2010). Deficiencies in trial design and inaccurate reporting, can lead potentially to the publication of biased estimates of treatment effects, placing limitations on the research (Altman 2002). However, well-designed studies are not sufficient in themselves to ensure transparency in empirical nursing research, not publishing negative or detrimental studies is a limitation to inform the state of the science and is also a form of scientific misconduct (Al-Marzouki et al., 2005). It is the presentation of evidence that is of utmost importance in a published scientific article.

We aim to publish the highest quality research papers that have relevance to several groups including; researchers, educators, policy-makers, clinicians and

patients. We have long supported the use of reporting guidelines to ensure that our publications, including systematic reviews, have transparency and can be judged appropriately by our readers.

In this editorial, we outline the rationale for adopting the range of reporting guidelines that we endorse at the *Journal of Clinical Nursing* and highlight the necessity of trial registration. Although most attention in the biomedical literature has been given to the remit of reporting guidelines in quantitative research, reporting guidelines have a role in all types of research. This editorial will emphasise reporting guidelines and trial registration for quantitative research methods. Attention will be given to the place of reporting guidelines in qualitative studies in a future (subsequent) editorial.

To have confidence that a study's findings accurately reflect intervention effectiveness depends on proper trial conduct and the accuracy and completeness of published study reports (Chalmers & Glasziou 2009). Poor reporting practices may seriously distort the published evidence, compromising its worth and reliability. Indeed, inadequate reporting may render a study's findings redundant (Jull & Aye 2015).

Commonly reported issues in poor quality research design can include failure to disclose a primary analysis; the non-reporting or delayed reporting of complete studies; omission of critical information in the description of study methods; insufficient description of interventions; presenting facts in a misleading way; and omissions from or misinterpretation of results in abstracts. All of these deficiencies have potentially serious consequences for clinical practice, research, education, policymaking and, ultimately, the care and safety of patients (Simera et al 2008).

As a response to sub-optimal quality of reporting of biomedical research, including nursing research, guidelines for several different types of study design have been developed by EQUATOR© to ensure accurate reporting and transparency for reviewers, readers from the scientific community and general public.

What is EQUATOR©?

EQUATOR© research reporting guidelines provide specific recommendations for the reporting of different types of research. Experts in study design, epidemiology, biostatistics, and research methodology have produced several EQUATOR© guidelines (Altman & Moher 2014). Many of these reporting guidelines include detailed checklists of items that can be included within a

manuscript as part of the submission process, in some guidelines a flow diagram displaying the progress of study participants is incorporated.

The CONSORT statement flow diagram provides a simple outline of how a study population was recruited and handled during the course of a study. Use of reporting guidelines can augment the transparency in the reporting of scientific research, making possibly easier for readers to assess and evaluate the quality of the study. Failure to follow the acknowledged international guidelines makes it difficult for readers to fully assess a study's rigour and transparency (Simera et al 2008). Presently, any study that fails to adhere to these reporting guidelines may be considered to have a risk of bias even if the study has been conducted rigorously.

Advantages of EQUATOR Compliance

It may be reasonable for authors to ask how EQUATOR guidelines can help the overall quality of their published research. From the perspective of *Journal of Clinical Nursing*, it is clear that the use of reporting guidelines can benefit academic nursing at several levels enhancing the profession as outlined in this editorial, enhancing our research integrity and transparency.

For potential journal authors, compliance with the appropriate EQUATOR reporting guidelines provides editorial offices with an indicator of the thoroughness of a submission. However, there are additional advantages that compliance provides to manuscript submission (Johansen & Thomsen 2016). Authors should not view reporting guidelines as an imposition, but as a handy author tool to enhance the quality of submissions (Altman & Simera 2010). The work of reviewers and editors when reviewing papers is made much easier when a consistent and readily recognizable submission structure is presented, potentially speeding up the decision time.

Within the *Journal of Clinical Nursing* author guidelines we actively encourage our authors to state limitations in their study. It is clear that no research study is absolutely perfect and increasing transparency in manuscripts may reveal additional limitations within a study. This need not prevent publication as editors and reviewers will be able to make an informed judgement about limitations, if presented in a transparent fashion.

At present, the *Journal of Clinical Nursing* endorses the following quantitative reporting guidelines:

Randomized (and quasi randomized) controlled trials: **CONSORT** –consolidated standards of reporting trials (Schultz et al 2010)

Observational, cohort, case control and cross-sectional studies: **STROBE**-strengthening the reporting of observational studies in epidemiology (von Elm et al. 2008).

Systematic review of controlled trials: **PRISMA**- preferred reporting items for systematic reviews and meta-analyses (Moher et al).

It is fully anticipated that in time more and more reporting guidelines will be endorsed by biomedical academic journals including nursing journals. Indeed, other quantitative reporting guidelines are emerging all the time, including **SAMPL** (Basic statistical reporting for articles published in biomedical journals: the "Statistical Analyses and Methods in the Published Literature" or the SAMPL Guidelines), however the same level of evidence as CONSORT or PRISMA does not support these (Lang & Altman 2015).

Trial registration

Since 2005, the International Committee of Medical Journal Editors (ICMJE) has required trial registration in public trial registries prior to patient enrolment for studies to be considered for publication (ICMJE 2016). Trial registration policies consistent with the ICMJE policy have been widely adopted across many biomedical journals, including *Journal of Clinical Nursing*. ICMJE guidelines require a priori specification of the primary and secondary outcomes in the trial registration (De Angelis et al 2004).

To date, many nurse researchers may not be fully aware of the need for prospective trial registration on a WHO-compliant register or the ethical considerations of non-registration. The International Clinical Trials Registry Platform (ICTRP) is a global initiative that aims to make information about all clinical trials involving human beings publicly available (World Health Organization 2012). Registration is not a time-consuming or costly procedure. Through adherence to the CONSORT statement, we effectively ensure that registration is required for all clinical trials. As highlighted by Gray et al (2017), there remains a need to develop a greater awareness among nurse authors and reviewers of the importance of trial registration.

Poor study reporting cannot be as an isolated issue that can be fixed by targeting one of the parties involved in the publishing process, be it authors, editors or reviewers. A well-coordinated approach between ethics, governance, research and publishing communities is most likely to influence the quality of future research publications (Hale & Griffiths 2015). In our view, all nursing journal editors need to be explicit about the need for authors to register trials when appropriate.

Our solution to inadequate reporting may lie with a more robust editorial position on adherence to reporting guidelines (the CONSORT Statement) and trial registration, as well as ensuring reviewers and all involved in the editorial process understand and adhere to the necessity of adequate reporting. ICMJE have suggested that if the author is uncertain whether their study meets the definition for a clinical trial that they should err on the side of registration (ICJME, 2016).

Use of Consolidated Standards of Reporting Trials (CONSORT) for RCTs along with prospective registration of all clinical trials can assist in assuring that appropriate information needed is present, potentially speeding up the peer review process. Endorsment of trial registration and CONSORT requirements by journal editorial teams should enhance the peer review process by providing authors and reviewers with the tools to ensure that they can effectively implement these requirements (Simera et al 2010).

Improving consistency in reporting requires the nursing publishing community to promote adherence as a collective; to not publish trials that are not adequately reported and registered on a WHO compliant trials register where appropriate. This would be a good starting point to enhance research integrity, and would address concerns raised by Gray et al (2017).

Descriptions of intervention and control groups as reported in a paper reporting an RCT should identically match information provided on the trial registration site. In addition, primary outcomes should be analyzed as indicated. At the *Journal of Clinical Nursing*, questions used to obtain this information are part of the online manuscript submission process.

Journal editors and reviewers have a responsibility to assure that study manuscripts are consistent with what has been registered and should not preferentially publish trials with positive findings at the expense of those with negative results (Wager & Williams 2013). Hence, nursing journal editors, publishers, funding agencies, ethics and governance committees, and professional and academic associations can all play a role in advocating for the implementation of trial registration. Beyond the *Journal of Clinical Nursing*, the scientific community, including researchers, other journals, academic institutions, and funders, would serve the public better if more attention were paid to the accurate and transparent reporting of clinical trials of nursing research.

References

- Al-Marzouki, S., Roberts, I., Marshall, T., & Evans, S. (2005). The effect of scientific misconduct on the results of clinical trials: a Delphi survey. *Contemporary Clinical Trials*, 26(3), 331-337.

Altman D & Simera I (2010) Responsible reporting of health research studies: transparent, complete, accurate and timely. *Journal of Antimicrobial Chemotherapy*; 65: 1-3.

Altman D (2002) Poor quality medical research: what can journals do? *JAMA* 287, 2765-2767.

Altman D & Moher D (2014) Importance of transparent reporting of health research (Chapter 1). In *Guidelines for Reporting Health Research: A user's manual*. (1st Edition) John Wiley & Son Publishing Ltd.

Chalmers I & Glasziou P (2009) Avoidable waste in the production and reporting of research evidence. *Lancet*, 374, 86-89.

De Angelis C, Drazen JM, Frizelle FA, Haug C, Hoey J, Horton R, (2004) Clinical trial registration: a statement from the International Committee of Medical Journal Editors. *The New England Journal of Medicine*; 351(12):1250-1.

Gray et al. *Registration of randomized controlled trials in nursing journals Research Integrity and Peer Review* (2017) 2:8

Hale C & Griffiths P (2015) ensuring the reporting quality of publications in nursing journals: A shared responsibility. *International Journal of Nursing Studies* 1025-1028.

Henly S & Chyun D (2017) Trial Registration: Lessons Learned From Nursing Research, *Nurse Editor and Author*, 27(1), 2

International Committee of Medical Journal Editors. (2016). Clinical trial registration (within Recommendations). Retrieved from: <http://icmje.org/recommendations/browse/publishingandeditorial-issues/clinical-trial-registration.html> (accessed 25th August 2017)

Johansen, M., & Thomsen, S. F. (2016). Guidelines for Reporting Medical Research: A Critical Appraisal. *International Scholarly Research Notices*, 2016, 1346026. <http://doi.org/10.1155/2016/1346026>

Jull A & Aye P (2015) Endorsement of CONSORT guidelines, trial registration and the quality of reporting randomized controlled trials in leading nursing journals *International Journal of Nursing Studies* 52; 1071-1079

Krleza-Jerić, K., Chan, A., Dickersin, K., Sim, I., Grimshaw, J., & Gluud, C. (2005). Principles for international registration of protocol information and results from

human trials of health related interventions: Ottawa statement (part 1). *BMJ (Clinical Research Ed.)*, 330(7497), 956-958. Lang TA & Altman DG. (2015) Basic statistical reporting for articles published in biomedical journals: the "Statistical Analyses and Methods in the Published Literature" or the SAMPL Guidelines. *International Journal of Nursing Studies*.52 (1): 5-9.

Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. *PLoS Med* 6 (7).

Schulz KF, Altman DG, Moher D (2010) CONSORT 2010 Statement: updated guidelines for reporting parallel group randomized trials. *British Medical Journal*; 340:c332

Simera I, Moher D & Hirst A (2010) Transparent and accurate reporting increases reliability, utility, and impact of your research: reporting guidelines and the EQUATOR Network. *BMC Medicine* 8, 24.

Simera I, Altman D, Moher D, Schulz K & Hoey J (2008) Guidelines for reporting health research; the EQUATOR Network's survey of guideline authors. *PLoS* 5, 6, e139.

Wager, E., Williams, P., (2013) Project Overcome failure to Publish Negative Findings 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* 347, f5248.

World Health Organization. (2016). International Clinical Trials Registry Platform (ICTRP). WHO Data Set. Retrieved from <http://www.who.int/ictrp/network/trds/en/> (accessed 25th August 2017)

von Elm E, Altman DG, Egger M, Pocock SJ, Gøtzsche PC, Vandenbroucke JP; STROBE Initiative (2008) The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting observational studies. *J Clin Epidemiol. Apr*;61(4):344-9.