Registration of Nurse-Initiated Clinical Trials

Why, How, When?

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Nursing Research adheres to the World Health Organization (WHO) definition of a clinical trial as “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” (WHO, 2014a). Clinical trials are not limited to evaluation of medications or devices and may consist of a variety of interventions, including procedures, behavioral therapy, process-of-care changes, and preventive care. In identifying a trial, the focus is not on the type of outcome under study, but that the study participants have been assigned to treatment, control, or comparison groups. As of January 1, 2015, Nursing Research will require that all clinical trials must be registered in an acceptable database as identified by WHO (2014b) or the International Committee of Medical Journal Editors (ICMJE, 2013a) in order to be reviewed and considered for publication. Pilot studies or secondary analyses will not require registration; however, the parent study registration for all secondary analyses should be documented.

Why? In the United States, the Food and Drug Administration Modernization Act of 1997 required the establishment of a registry of clinical trials for both federal and privately funded trials for new drug applications; this registry was available to the public beginning in February 2000 (“History, policies, and laws,” 2013). Registration requirements were expanded in the Food and Drug Administration Amendments Act of 2007 Section 801, which required that more types of trials be registered and that results be submitted for certain trials. The database, which includes summary results and adverse events, was made available to the public in September 2008. Further regulations are expected in order to provide more complete reporting and improve information available to the public. In 2008, the Declaration of Helsinki—Ethical Principles for Medical Research Involving Human Subjects was amended to include prospective registration and public disclosure of study results—negative and inconclusive results, as well as positive—as ethical obligations. In October 2013, these principles were modified to include trial registration prior to enrollment of the first subject and the duty for all parties, including editors and publishers, to adhere to guidelines for ethical reporting (“History, policies, and laws,” 2013).

Ten years ago, the International Committee of Medical Journal Editors established mandatory registration of clinical trials for its 11 member journals (De Angelis et al., 2004). The editors recognized that the results of all trials, not just those with positive outcomes or those with outcomes that benefited the study’s sponsor, need to be available not only to the scientific community but also to the public. Mandating registration of clinical trials would provide a public record on all trials, regardless of outcome, and would contribute to scientific knowledge and informed decision-making. In addition to the need for honest and complete reporting of trial results, other reasons for trial registration include providing information for clinicians and potential subjects as well as enrollment opportunities, reducing publication bias, assisting editors and others to understand the context of study results, promoting efficient allocation of research funds, and assisting institutional review boards to determine study appropriateness (Zarin & Keselman, 2007). In addition, reporting of study results contributes to a public record in a standardized format, assuring that results contribute to scientific knowledge and ethical responsibilities are met, minimizing publication bias, and facilitating scientific literature reviews (Tse, Williams, & Zarin, 2009). Although results reporting is not universally mandated, accurate reporting is critical and deficiencies have been observed (Zarin, Tse, Williams, Califf, & Ide, 2011). Despite increases in registration and reporting, concern for timely and complete dissemination of study findings is real: Only 46% of clinical trials registered in ClinicalTrials.gov were published within 30 months of trial completion (Ross et al., 2012).

How? Register your clinical trial at an ICMJE- or WHO-approved site. The ICMJE accepts registration in the following registries: www.anzctr.org.au, www.clinicaltrials.gov, www.ISRCTN.org, www.umin.ac.jp/ctr/index.htm, www.trialregister.nl, and https://eudract.ema.europa.eu. The WHO International Clinical Trials Portal (WHO, 2014b) currently lists 15 acceptable registries. Necessary registry characteristics include that it should be electronically searchable and accessible to the public at no charge, open to all registrants and not for profit, and have a mechanism to ensure the validity of the registration data (De Angelis et al., 2004). In addition, registries must include 20 minimum data elements (ICMJE, 2013b). Include the trial site and your registration number in the letter to the editor that you submit with your manuscript.

When? Now. Register your trial so that you can include the required trial registration information beginning in 2015. Findings from clinical trials initiated by nurse scientists have made
substantial contributions to healthcare, particularly in the behavioral domain; yet, our work may not be widely disseminated and recognized by either colleagues or the public. The number of registered trials conducted by nurse scientists is not known. Trial registration and results reporting can only enhance the visibility, importance, and reach of nursing science. Please take the time to visit the ICMJE, WHO, and ClinicalTrials.gov sites, register your clinical trial and report your results, and submit your manuscript to Nursing Research!

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REFERENCES


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