

Registration of Clinical Trials: What Nurse Researchers Need to Know

Vishnu Renjith¹, Renjula Yesodharan², Anice George³

Abstract

Clinical trials registry is an official platform for registering a clinical trial. Trial registration refers to the publication of a set of information regarding the methods, conduct, and administration of clinical trials. Any researcher who plans to conduct a trial involving human participants can register the trial in the registry. Researchers can register their trials at any trial registry which conforms to standards of World Health Organisation (WHO). Clinical trial registration fulfills ethical obligations to participants and the research community. Registering a trial at the registry is considered as an ethical step towards the enhanced visibility, greater transparency, and accountability in undertaking clinical research.

Nurse researchers strive to maintain high standards of ethical practice during the conceptualisation and conduct of research. In the current scenario of evidence-based practice, nurse researchers are widely using clinical trials to inform their practice. A clinical trial is defined as “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, 2017).

Clinical trials registry is an official platform and a catalogue for registering the clinical trials. ‘ClinicalTrials.gov’ run by the United States National Library of Medicine (NLM) was the first online registry for clinical trials and is the largest clinical trial registry (Tharyan & Ghersey, 2008). International Committee of Medical Journal Editors (ICMJE) mandates trial registration as a condition for publication of results generated by a clinical trial (Laine et al, 2007). The trial registration aims to prevent the selective publication and selective reporting of study outcomes.

International Clinical Trials Registry Platform (ICTRP)

WHO’s International Clinical Trials Registry Platform (ICTRP) is a network of international clinical trial registries. It acts as the single point access, a search

portal for identification of clinical trials and enhances the access to clinical trial information by patients, families, and others.

Researchers can register their trials at any trial registry approved by a publically accessible registry which conforms to the WHO standards. WHO registry consists of primary registries and partner registries. Primary registries meet specific criteria under the areas of content, quality, validity, technical capacity, administration, etc. Partner registries do meet the criteria as primary registries; however, they need not have a national or regional remit, can be managed by a non-profit agency and be open to all prospective registrants.

WHO currently has 16 registries under the primary registries and three partner registries. Unlike primary registries, partner registries don’t meet the requirements for ICMJE. Clinical Trials Registry - India (CTRI) is a primary trial registry under WHO. Trial registration in CTRI is an online process, and it does not involve any payment.

There is a common misconception that the trial registration is limited to drug trials. Trials involving any interventions such as; surgical procedures, behavioural therapies, educational interventions, rehabilitation strategies, complementary or alternative therapies, the process of care changes, yoga, lifestyle modifications, nursing care innovations, preventive care, non-pharmacological interventions can be registered in a trial registry. All clinical trials, irrespective of being small or big must be registered with the clinical trial registry.

The authors are: 1. Jr Research Fellow, Dept of Medical-Surgical Nursing; 2. Lecturer, Dept of Mental Health Nursing; and 3. Professor, all at Manipal College of Nursing (Manipal Academy of Higher Education), Manipal (Karnataka).

When to register the trial?

A researcher can register the trial after getting the approval from the Institutional Review Board. The Helsinki Declaration states that "Every clinical trial must be registered in a publicly accessible database before recruitment of the first subject." Various medical, nursing, and allied health journals advocate prospective registration of clinical trials. It is strongly recommended that researchers register their trials in an approved trial registry before the commencement of their trials.

What is Clinical Trials Registry - India (CTRI)?

The Clinical Trials Registry - India (CTRI), a primary registry under ICTRP, is an online system for the registration of clinical trials being conducted in India. CTRI was launched on 20 July 2007 under the canopy of National Institute of Medical Statistics of the ICMR New Delhi with an objective to ensure that all clinical trials conducted in India are registered in order to bring transparency, accountability, and access to clinical trials (Tiffin & Nickerson, 2013).

The researchers can register their trials online and access the official details via the website: www.ctri.nic.in. While registering with CTRI, the researchers must disclose details of the 24 mandatory items of the WHO International Clinical Trials Registry Platform dataset. Currently, CTRI accepts registration of clinical trials where patient recruitment has already started or even completed. However, from 1 April 2018, CTRI will allow only prospective registration of trials. An e-learning tutorial detailing the processing of trial registration is available on the home page of CTRI. Being a primary registry under ICTRP, trials registered with CTRI are freely searchable via WHO's ICTRP portal as well as from CTRI website. As on 30 June 2017, the CTRI has registered 8950 trials of which 3318 were prospective, and 5604 were retrospective registrations.

Benefits of Registering a Clinical Trial

Clinical trial registration fulfils ethical obligations to participants and the research community. It enhances the visibility of the trial and helps Institutional review boards (IRBs) to determine the appropriateness of a research study. Trial registration helps editors and others to understand the context of study results. Registering trials provide information to potential participants and referring clinicians and it fulfills ethical obligations to participants and the research community. A priori registration of a clinical trial prevents non-reporting or selective reporting of trial results and reduces the publication bias. Patients, clinicians, the general public, IRBs, and other stakeholders are benefitted with the informa-

tion provided in the trial registry (Zarin & Keselman, 2007).

Conclusion

The future of evidence-based nursing practice depends upon methodologically rigorous and ethically sound clinical trials. Clinical trials initiated by nurse researchers have enormous potential to improve patient care, develop nursing care interventions and ensure that the practice is evidence-based. WHO considers registration of trial as a scientific, ethical and moral responsibility. Registering a trial at the registry is as an ethical step towards the enhanced visibility, greater transparency, and accountability in undertaking clinical research.

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