EDITORIAL

Clinical Trial Registration: The Time Has Come

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MeSH TERMS
- biomedical research
- clinical trials as topic
- editorial policies
- registrations
- research design

Note from the AJOT Editor-in-Chief: AJOT has joined several other major rehabilitation and disability journals in a collaborative initiative to mandate clinical trial registration. Authors of manuscripts reporting clinical trials must ensure that the trials are registered before submitting their manuscript. For trials that are underway and are already enrolling patients, registration will be retrospective. This interim step achieves the goals of educating authors about trial registration and providing documentation of original study designs and primary outcome measures. Multiyear studies that were not registered before enrolling participants, are ongoing at the time of this editorial, and will not be completed before the January 1, 2017, deadline may be considered for publication in *AJOT* with special permission from the Editor-in-Chief. This permission must be obtained before submitting the manuscript for publication. By adopting these standards, we hope to further enhance the quality of *AJOT* articles.

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Registration of a clinical trial requires that researchers document key aspects of their research methodology in a publicly available database. In the words of the International Committee of Medical Journal Editors, the registration of clinical trials is needed

> to prevent selective publication and selective reporting of research outcomes, to prevent unnecessary duplication of research efforts, to help patients and the public know what trials are planned or ongoing into which they might want to enroll, and to help give ethics review boards considering approval of new studies a view of similar work and data relevant to the research they are considering. (International Committee of Medical Journal Editors, n.d., para. 5)

Any journal that wants to follow the International Committee of Medical Journal Editors guidelines must require registration, and authors who state that they abide by the Declaration of Helsinki must register their trial before the first patient is enrolled. Trial registration is also required by regulations of the U.S. Food and Drug Administration, European Union, and World Health Organization (https://clinicaltrials.gov/ct2/manage-recs/background).

Some rehabilitation research consortiums (e.g., International Society of Physiotherapy Journal Editors) have transitioned to mandatory trial registration. We refer our readers to their 2013 editorial that clearly outlines the case for mandatory trial registration and the details of how authors may comply (Costa et al., 2013).

In brief, trial registration has been gaining adherents since the concept was proposed in the late 1990s. For our purposes (please refer to the instructions for authors for each journal because this definition may vary), a clinical trial is defined 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" (World Health Organization, 2015, para. 3). Therefore, cohort and retrospective studies without an intervention do not require registration, and neither do observational studies of clinical care. However, studies of human

subjects with prospective assignment of an intervention by the investigators, regardless of the size of the trial or method of assignment, must be registered.

There are a number of free websites where researchers can register their trials. Perhaps the most frequently used in the United States are the following: ClinicalTrials.gov (available at https://clinicaltrials.gov/ct2/manage-recs) and International Clinical Trials Registry Platform (available at http://www.who.int/ictrp/en/). There are also country-specific sites; however, most registries will take data from any nation.

This editorial serves as a notice to authors that they must register their trials soon. Starting January 1, 2016, all manuscripts reporting clinical trials must be registered before submission. For trials that are underway and are already enrolling patients, registration will be retrospective. This interim step achieves 2 goals: (1) to educate authors about trial registration, and (2) to provide documentation of original study designs and primary outcome measures.

This transition period will end January 1, 2017. By that time, all journals publishing this editorial will only consider clinical trials that have been registered before the first patient is enrolled.

We take these steps with the goal of enhancing the quality of the science we publish and improving the health of patients around the world. ▲

Acknowledgments

As this issue went to press, the following editors had agreed to participate in the initiative to mandate clinical trial registration and publish this Position Statement, or a similar statement, in their respective journals. As a collective group, we encourage others to adopt these guidelines and welcome them to share this editorial with their readerships.

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