Special Issue on the Accelerating Clinical Trials and Outcomes Research (ACTOR) Conference

Susan H. Lin

MeSH TERMS
- clinical trials as topic
- evidence-based practice
- occupational therapy
- research
- treatment outcome

Many occupational therapy practitioners enter the profession to help improve people’s lives, but how do we know that our treatments work? The answer lies not with techniques and modalities; instead, our treatments work because of theories and research. The role of research in education, practice, and policy continues to grow, and accordingly research is highlighted in the Centennial Vision with the words “science-driven” and “evidence-based” (American Occupational Therapy Association [AOTA], 2007).

The emphasis on research is timely given the increasing health care needs of society, and yet we have made little progress in generating the evidence needed to support our role in today’s rapidly changing health care environment. An examination of studies published in the American Journal of Occupational Therapy (AJOT) between 1995 and 2005 revealed that the number of highly controlled studies (Level I and II) did not increase (Dirette, Rozich, & Viau, 2009), prompting an editorial emphasizing the urgent need for effectiveness studies (Gutman, 2008). As a result, the percentage of effectiveness studies published in AJOT has steadily increased from 24% in 2008 to 48% in 2011 (Gutman, 2011). Additional progress has been made in increasing research capacity, as evidenced by the addition of 15 research doctoral programs over the past 15 years and the increasing number of occupational therapists receiving postdoctoral fellowships and career development (K) awards.

Meanwhile, the Research Advisory Panel of AOTA and the American Occupational Therapy Foundation (AOTF), chaired by Joan Rogers, developed a research agenda for the profession emphasizing intervention research as a priority (AOTA & AOTF, 2011). Despite the proliferation of clinical trials in medical science, clinical trials that examine complex rehabilitation interventions and long-term outcomes have been conducted at a slower rate because of the wide scope of factors related to disability and goals and the difficulty in standardizing treatments and outcomes (Johnston et al., 2009). Moreover, methods and models of service delivery may influence rehabilitation outcomes as much as individual components (i.e., therapies; Whyte & Hart, 2003). Thus, a limited number of Level I studies are available from rehabilitation and disability research to guide practice.

ACTOR Conference

From this context, a synergistic initiative by AOTA and AOTF emerged, resulting in a research conference, the Accelerating Clinical Trials and Outcomes Research (ACTOR) Conference, which took place December 1–2, 2011. The purpose of the conference was to accelerate the pace of generating rigorous clinical trials and outcomes research to inform the decision making of consumers, policymakers, and clinicians. The conference drew 85 early- to midcareer researchers from several institutions.
rehabilitation disciplines but predominantly from occupational therapy.

The ACTOR Conference’s success was attributable in large part to the excellent speakers and dynamic discussions by attendees. This special issue featuring select presentations of the conference is one of the dissemination methods.

In the article “Protocol Development, Treatment Fidelity, Adherence to Treatment, and Quality Control,” Persch and Page (2013) describe the process of creating an intervention protocol and refer to the Consolidated Standards of Reporting Trials (CONSORT; Moher et al., 2012) and the Transparent Reporting of Evaluations with Non-Randomized Designs (TREND; Des Jarlais, Lyles, & Crepaz, 2004). Persch and Page also discuss sample size, power, randomization, and the manual of procedures (MOP). The MOP includes a study’s organization, operational definitions, procedures, data flow, forms, and quality control procedures. Guiding questions and pragmatic advice from Persch and Page help demystify the protocol development phase.

Next, Page and Persch (2013) address common issues associated with clinical trials in their article “Recruitment, Retention, and Blinding in Clinical Trials.” They cite common pitfalls in these important steps of clinical research, offering practical strategies with respect to the study’s design and procedures. They also provide helpful ideas about pilot trials and passive and active recruiting. Finally, they share strategies for retaining participants throughout the study and for blinding (e.g., single, double, and triple blinding) to prevent biased results, which is particularly important for behavioral interventions.

One of the most critical steps in designing intervention studies is selecting the outcome measures. In “Making the Best Match: Selecting Outcome Measures for Clinical Trials and Outcome Studies,” Coster (2013) urges researchers to delve deeper than psychometric properties (e.g., validity and reliability) when selecting outcome measures. She provides a set of guiding questions to help researchers determine the best measure covering item bias, sensitivity to capturing change, and procedural issues such as who should provide outcome information and when.

To help researchers focus on the pragmatics of conducting clinical trials, presenters offered a more in-depth view of the experience and continuum of clinical trials. Tickle-Degnen (2013) distinguishes between the purposes and characteristics of feasibility studies, pilot studies, and randomized controlled trials in her article “The Nuts and Bolts of Conducting Feasibility Studies.” She refers to Thabane et al.’s (2010) typology of feasibility and pilot studies, which can be modified for rehabilitation intervention research. Tickle-Degnen’s example of a feasibility study, complete with guiding questions, offers a useful process for thinking through such a study that then informs the subsequent pilot study.

Providing a broader view of the research process, Gitlin (2013) reviews the traditional four-phase model of developing interventions (discovery; Phase 1, feasibility; Phase 2, exploratory; Phase 3, efficacy; Phase 4, dissemination and implementation) in her article “Introducing a New Intervention: An Overview of Research Phases and Common Challenges.” Although this traditional model’s timeline is lengthy, newer hybrid models that incorporate stakeholders and test phases may offer quicker results with more clinical relevance.

Following this overview of challenges and opportunities for behavioral intervention research, Clark (2013) reminds researchers to consider implementation strategies early on so we can reduce the gap between the generation of evidence and the routine incorporation of evidence in clinical practice. In her article “Dissemination: Bringing Translational Research to Completion,” Clark describes the emerging field of implementation science by contrasting the dissemination methods of A. Jean Ayres’ sensory integration therapy and the University of Southern California’s Well-Elderly Studies. Developing an implementation plan can help accelerate clinicians’ and consumers’ uptake of the intervention and more quickly influence policymakers’ decision making. Clark reviews the phases of translational research and the RE-AIM framework (Glasgow, Vogt, & Boles, 1999), which facilitates implementation of the intervention. To establish an intervention’s efficacy is not enough—researchers also need to consider whether the intervention is broadly applicable and has reach. In this way, researchers and practitioners are striving for the same goal: to improve the everyday lives of members of society.

**Conclusion**

The emphasis on evidence-based practice and the multiplicity of interventions used in rehabilitation create an unprecedented need to expand research capacity. Occupational therapy needs more researchers to conduct rigorous intervention studies to answer critical questions facing the profession. Training additional scientists to conduct clinical trials and outcome studies will lay the foundation for the delivery of efficacious and effective habilitation and rehabilitation practices. The ACTOR Conference provided researchers a starting point for shared learning and dialogue, and with the help of researchers, clinicians, educators, and students, occupational therapy will emerge as an evidence-based and science-driven profession meeting society’s occupational needs.

**Note**

AOTA and AOTF are proud to announce the availability of free resources from the Accelerating Clinical Trials and Outcomes Research (ACTOR) Conference held on Dec. 1–2, 2011, with the generous support of the Agency for Healthcare Research and Quality:

- Videos of all presentations and discussions are available at http://vimeo.com/album/1834514.
- PowerPoint presentations are available at https://sites.google.com/site/actorresearchconference/conference-powerpoint-presentations.

**Acknowledgments**

The ACTOR Conference was supported by the Agency for Healthcare Research and Quality (1 R13 HS020560-01A1) and by AOTA and AOTF. Thanks to Jeanne Cooper and Charles Christiansen at AOTF for their assistance and support.
References


