Clinical Trials in Neuropsychological Rehabilitation: Challenges and Solutions

Clinical trials aimed at improving neuropsychological function are increasingly important for developing the evidence base for both pharmacologic and behavioral (experience-based) interventions. In this workshop, we will review and discuss both conceptual and practical issues involved in designing and implementing clinical trials targeting cognitive, psychological and behavioral change. We review basic trial designs and their strengths and weaknesses with respect to internal and external validity; issues involving the selection or design of appropriate control conditions; and special problems such as masking. Issues related to experimental treatment implementation are also discussed, including therapist allocation and training, and assessment of treatment fidelity. While n-of-1 designs will be touched on, most of the workshop content will focus on group studies. Also addressed will be “macro” issues germane to clinical trial design such as consideration of the state of existing knowledge and the challenges of specifying the active ingredients in the complex, learning-based interventions that are widely used in neuropsychological rehabilitation. We will make frequent reference to a developmental framework in which different designs may be appropriate for addressing the distinct goals of different phases of research, from initial proof-of-concept studies to definitive clinical effectiveness trials.

At the conclusion of this presentation, attendees will be able to: (1) Describe at least 2 types of control conditions for behavioral clinical trials and the advantages and disadvantages of each; (2) Explain what masking is and list at least methods of achieving optimal masking in a behavioral clinical trial; (3) Describe at least 3 phases of research that may be needed along the trajectory toward clinical effectiveness studies, and the goals of each phase