

Guidelines for Trials of Behavioral Treatments for Recurrent Headache: Purpose, Process, and Product

Donald B. Penzien, PhD

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The behavioral clinical trials guidelines presented in this supplement¹ were developed to enhance the quality and consistency of research evaluating behavioral treatments for primary headache disorders. Developed under the auspices of the American Headache Society (AHS), these guidelines are complementary to and modeled after guidelines published by the International Headache Society to address research methodology apropos to drug trials for migraine,² tension-type headache,³ and cluster headache.⁴ Explicit guidelines for evaluating behavioral headache therapies are needed as the optimal methodology for behavioral (and other nonpharmacologic) trials necessarily differs from the preferred methodology for drug trials. In addition, trials comparing and integrating drug and behavioral therapies present methodological challenges not addressed by guidelines for pharmacologic research.

THE SPECIAL SERIES

The guidelines are complimented by a special series of articles addressing headache research methodology published in tandem with this supplement in the May issue of *Headache* (Vol. 45:5, 2005). This special series was in fact conceptualized during production of

the behavioral trial guidelines. Emerging from discussions and debates that took place during the guideline development, the thesis of each article in the series was judged to be a key methodological issue meriting further articulation and development expressly for headache investigators.⁵⁻²¹ The series is arranged in two sections, with the first examining headache research issues of general relevance⁷⁻¹² and the subsequent section addressing key design and methodological considerations for behavioral headache research.¹³⁻²⁰ The latter section includes an examination of conceptual and procedural challenges in applying research designs well suited to pharmacologic clinical trials when evaluating behavioral or other nonpharmacologic interventions¹⁴ as well as the special methodological issues that arise for trials comparing or integrating drug and behavioral therapies.¹⁵ Special consideration was devoted to headache research issues uniquely pertaining to children¹⁸ and patients with psychiatric disorders.¹⁶ The final article in the behavioral series enumerates unmet needs and priorities for evaluating behavioral headache therapies.²⁰

GUIDELINE INITIATIVE AND PROCESS OF DEVELOPMENT

These behavioral clinical trials guidelines were an initiative of the AHS's Behavioral Issues Section who in 2003 appointed the *Behavioral Clinical Trials Workgroup* (Dr. Donald Penzien, Chair). The Workgroup initially met during the AHS annual scientific meeting in Chicago (June 2003); an outline of the guideline was

From the Department of Psychiatry and Human Behavior, and Director, Head Pain Center, University of Mississippi Medical Center, Jackson, Mississippi.

Address all correspondence to Dr. Donald B. Penzien, Head Pain Center Department of Psychiatry and Human Behavior University of Mississippi Medical Center, 2500 North State Street, Jackson, MS 39216.

reviewed and plans were made for preparation of a draft document for discussion at a working retreat. The retreat took place in February 2004, sponsored by the AHS and the Duke Center for Clinical Health Policy Research in Durham, NC (Dr. Douglas McCrory) with most Workgroup members in attendance. In a series of fruitful meetings, the Workgroup reviewed the draft document, extensively discussed the more controversial issues, and formulated specific recommendations for inclusion in the guideline. Revisions were subsequently undertaken and revised drafts were circulated to Workgroup members for review and comment. Additional Workgroup meetings were held during the AHS's scientific meeting (Vancouver, June 2004) to finalize a draft for presentation to the AHS Board of Directors. The draft was presented to the Board at their November 2004 meeting who created an Ad Hoc Committee for guideline review (Dr. Joel Saper, Chair). Also, in November, the Workgroup posted the guideline on the Internet and invited public comment. Notification of the posting was circulated via listservs maintained by the AHS Behavioral Issues Section and the Society of Behavioral Medicine. In response, a great deal of constructive critique was offered and integrated into subsequent drafts. The present version of the guideline was reviewed and sanctioned by the AHS Board in March 2005.

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