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

Donald B. Penzien, PhD

(*Headache* 2005;45[Suppl 2]:S87-S89)

The behavioral clinical trials guidelines presented in this supplement[1] 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 relevance[7-12] 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 interventions[14] 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 children[18] 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.

Acknowledgments: There are many who merit recognition and gratitude for this endeavor. Tremendous credit is due Dr. Jason Roberts, managing editor of Headache for his innumerable contributions to the production of this supplement and the special series. Great appreciation is extended to Dr. John Rothrock, editor in chief, for providing unrestricted support and encouragement for this effort, as well as to Dr. Morris Maizels who served as coeditor for the accompanying special methodology paper series. Blackwell Publishing deserves great thanks for generously sponsoring production of this supplement. Thanks again to Dr. Rothrock, and to supplement editors Dr. Alan Rapoport and Dr. Allan Purdy for dedicating resources for this purpose and for their oversight of supplement development.

I am also pleased to acknowledge that this supplement and the companion series of methodology articles are products of the AHS's special interest section initiative. The AHS has fully supported the Behavioral Clinical Trials Workgroup and the Behavioral Issues Section in their efforts to bring the guideline and the special series to fruition. Finally, I extend my sincere gratitude to the members of the Workgroup: Drs. Frank Andrasik, Brian M. Freidenberg, Timothy T. Houle, Alvin E. Lake, III, Gay L. Lipchik, Kenneth A. Holroyd, Richard B. Lipton, Douglas C. McCrory, Justin M. Nash, Robert A. Nicholson, Scott W. Powers, Jeanetta C. Rains, and David A. Wittrock. An overarching aspiration of Workgroup authors is that publication of this behavioral trials guideline and the special methodology series will foster new innovative and ambitious research examining headache disorders.

REFERENCES

1. Penzien DB, Andrasik F, Freidenberg BM, et al. Guidelines for trials of behavioral treatments for recurrent headache. *Headache*. 2005;45:S110-S132.
2. Tfelt-Hansen P, Block G, et al. Guidelines for controlled trials of drugs in migraine. 2nd ed. *Cephalalgia*. 2000;20:765-778.
3. Schoenen J, Boureau F, Kunkel R, et al. Guidelines for trials of drug treatments in tension-type headache. 1st ed. *Cephalalgia*. 1995;15:165-179.
4. Lipton RB, Micieli G, Russell D, et al. Guidelines for controlled trials in cluster headache. 1st ed. *Cephalalgia*. 1995;15:452-461.
5. Penzien DB. Headache research methodology: introduction to the special series. *Headache*. 2005;45:408-410.
6. Maizels M. Why should physicians care about behavioral research? *Headache*. 2005;45:411-413.
7. Houle TT, Penzien DB, Houle CK. Statistical power and sample size estimation for headache research: an overview and power calculation tools. *Headache*. 2005;45:414-418.
8. Lipchik GL, Nicholson RA, Penzien DB. Allocation of patients to conditions in headache clinical trials: randomization, stratification, and treatment matching. *Headache*. 2005;45:419-428.
9. Andrasik F, Lipchik GL, McCrory DC, Wittrock DA. Outcome measurement issues in headache research: headache parameters and psychosocial outcomes. *Headache*. 2005;45:429-437.
10. Houle TT, Remble TA, Houle TA. The examination of headache activity using time-series research designs. *Headache*. 2005;45:438-444.
11. Houle TT, Penzien DB, Rains JC. Time-series features of headache: individual distributions, patterns,

and predictability of pain. *Headache*. 2005;45:445-458.
12. McCrory DC, Gray RN, Tfelt-Hansen P, Steiner TJ, Taylor FR. Methodological issues in systematic reviews of headache trials: adapting historical diagnostic classifications and outcome measures to present-day standards. *Headache*. 2005;45:459-465.
13. Hursey KG, Rains JC, Penzien DB, Nash JM, Nicholson RA. Behavioral headache research: methodologic considerations and research design alternatives. *Headache*. 2005;45:466-478.
14. Rains JC, Penzien DB. Behavioral research and the double-blind placebo-controlled methodology: challenges in applying the biomedical standard to behavioral headache research. *Headache*. 2005;45:479-486.
15. Holroyd KA, Powers SW, Andrasik F. Methodological issues in clinical trials of drug and behavior therapies. *Headache*. 2005;45:487-492.
16. Lake AE III, Rains JC, Penzien DB, Lipchik GL. Headache and psychiatric comorbidity: historical context, clinical implications, and research relevance. *Headache*. 2005;45:493-506.
17. Nash JM, McCrory D, Nicholson RA, Andrasik F. Efficacy and effectiveness approaches in behavioral treatment trials. *Headache*. 2005;45:507-512.
18. Nicholson RA, Hursey KG, Nash JM. Moderators and mediators of behavioral intervention for headache. *Headache*. 2005;45:513-519.
19. Andrasik F, Powers SW, McGrath PJ. Methodological considerations in research with special populations: children and adolescents. *Headache*. 2005;45:520-525.
20. Penzien DB, Rains JC, Lipchik GL, Nicholson RA, Lake AE III, Hursey KG. Future directions in behavioral headache research: applications for an evolving healthcare environment. *Headache*. 2005;45:526-534.
21. Lipton RB, Bigal ME. Editorial. *Headache*. 2005;45:535-537.