Summer Training Institute for Randomized Clinical Trials Involving Behavioral Interventions

Tab 6 Course Bibliography¹

*Ader, R. & N. Cohen, Behaviorally conditioned immunosuppression and murine systemic lupus erythematosus, *Science*, 1982, 215, 1534-6.

²Armstrong, P. W., and C. D. Furberg, Clinical trial data and safety monitoring boards, *Ciculation*, 1995, 91, 901-904.

Beecher, H. K., The powerful placebo. JAMA³, 1955, 27, 1602-1606.

*Begg, C., *et al.*, Improving the quality of reporting of randomized controlled trials, *JAMA*, August 28, 1996, *276* (3), 637-639.

*The Belmont Report: Ethical principles and guidelines for the protection of human subjects of research, April 18, 1979 (Department of Health, Education, and Welfare)

Blumenthal JA, Jiang W, Babyak MA, Krantz DS *et al.* Stress management and exercise training in cardiac patients with myocardial ischemia. Effects on prognosis and evaluation of mechanisms. *Arch Intern Med*⁴ 1997; 157:2213-2223.

*Brody, B. A., *The Ethics of Biomedical Research: An International Perspective*. New York: Oxford University Press, 1998, pp. 72-75 & Chapter 7.

*Buyse M, *et al*. The role of biostatistics in the prevention, detection and treatment of fraud in clinical trials. *Statistics in Medicine*, 1999; *18*, 3435-3451.

*Cappelleri, J. C., *et al.*, Large trials vs. meta-analysis of smaller trials: How do the results compare? *JAMA*, October 23/30 1996, 276 (16), 1332-1338.

*Code of Federal Regulations, Title 21, Section 314.126, Adequate and Well-controlled Studies.

*Code of Federal Regulations, Title 45, Part 46, Subpart A, Projection of Human Subjects.

Coronary Drug Project Research Group, Influence of adherence to treatment and response of cholesterol on mortality in the Coronary Drug Project, *N Engl J Med*⁵, 1980, 303: 1038-1041.

DeMets, D. L., Data monitoring and sequential analysis: An academic perspective. *Journal of Acquired Immune Deficiency Syndrome*, 1990, 3 (Supplement), S124-S133.

Der Simionian, R. Meta-analysis in the design and monitoring of clinical trials, *Statistics in Medicine*, 1996, *15*, 1237-1248

¹ An asterisk (*) indicates a *Required Reading* All required readings are located behind the tab in this binder for the associated lecture. When available, reprints of *Suggested Readings* are located immediately following this bibliography in alphabetical order of the author's last name.

² **Bold** type indicates a copy of the *Suggested Reading* article is reprinted.

³ Journal of the American Medical Association

⁴ Archives of Internal Medicine

⁵ New England Journal of Medicine

Bibliography

Diggle, PJ, Liang, KY, Zeger, SL, Analysis of Longitudinal Data. Oxford Science Publications, 1998. Chapter 1, pp. 1-22.

Discussion, Statistics in Medicine, 1996, 15, pp. 1259-1262, 1281-1283, and 1307-1311.

*Domanski, M. J., and L. M. Friedman, Relative role of meta-analysis and randomized controlled trials in the assessment of medical therapies, American Journal of Cardiology, 1994, 74, 395-396.

Frasure-Smith N, Lesperance F, Prince RH, Verrier P et al. Randomised trial of home-based psychosocial nursing intervention for patients recovering from myocardial infarction. Lancet 1997; 350: 473-479.

*Frasure-Smith N & Prince R, Long-term follow-up of the Ischemic Heart Disease Life Stress Monitoring Program, *Psychosom Med*⁶, 1989, 51, 485-513.

*Friedman LM, Furberg CD, and DeMets DL, Fundamentals of Clinical Trials, Third Edition. New York: Springer-Verlag, 1998, selected chapters.

*Geller, N. L., and M. Proschan, Meta-analysis of clinical trials: A consumer's guide, Journal of Biopharmaceutical Statistics, 1996, 6 (4), 377-394.

Ghosh, D., Methods for analysis of multiple events in the presence of death, Control Clin Trials, 2000, 21, 115-126.

Green, S. B., The advantages of community-randomized trials for evaluating lifestyle modification, Controlled Clinical Trials, 1997, 18, 506-513

*Hallstrom, A. P., & S. D. Sullivan, On estimating costs for economic evaluation in failure time studies, *Medical Care*, 1998, 36 (3), 433-436.

Hallstrom, A. P., et al. Advantages and disadvantages of trial designs: A review of analysis methods for ICD studies, Pace, 2000, 23, 1029-1038.

*Harris, WS, et al., A randomized controlled trial of the effects of remote, intercessory prayer on outcomes in patients admitted to the coronary care unit, Arch Intern Med, 1999, 159: 2273-2278.

*Helsinki Declaration: Ethical Principles for Medical Research Involving Human Subjects (World Medical Association), revised October 2000.

*Hrobjarstson, A. & P. C. Gotzsche, Is the placebo powerless? An analysis of clinical trials comparing placebo with no treatment. New England Journal of Medicine, 2001, *244*, 1594-1602.

*Infant Health and Development Program, Enhancing the outcomes of low-birth-weight, premature infants, *JAMA*, June 13, 1990, 263 (22), 3035-3042.

Jones DA & West RR. Psychological rehabilitation after myocardial infarction: Multicentre randomised controlled trial. BMJ^7 , 1996; 313: 1517-1521.

Tab 6, Page 2 7/12/2001

⁶ Psychosomatic Medicine

⁷ http://www.bmj.com

Bibliography

- Keefe, F. J., *et al.*, Pain coping skills training in the management of osteoarthritic knee pain: A comparative study. *Behavior Therapy*, 1990, 21, 49-62
- *Knatterud, G. L., *et al.*, Guidelines for quality assurance in multicenter trials: A position paper. *Controlled Clinical Trials*, 1998, *19*, 477-493.

Knatterud, G. L., Why clinical trials in the evaluation of life style evaluation? *Controlled Clinical Trials*, 1997, 18, 514-516.

- *Letters to the Editor, *JAMA*, December 9, 1998, 280 (22), 1905-1908
- *Martin KA, *et al.*, Who will adhere? Key issues in the study and prediction of adherence in randomized controlled trilas, *Controlled Trials*, 2000, 21, 195S-199S
- *Meinert C. L. *Clinical Trials: Design, Conduct and Analysis*. Chapter 16, "Quality Assurance." New York, New York: Oxford University Press, 1986, pages 166-176.
- *The Cardiac Arrhythmia Suppression Trial (CAST) Investigators, Preliminary report: Effect of encainide and flecainide on mortality in a randomized trial of arrhythmia suppression after myocardial infarction, *N Engl J Med*, 1989, *321*: 406-412.
- *The MTA Cooperative Group, A 14-month randomized clinical trial of treatment strategies for Attention-Deficit/Hyperactivity Disorder, *Arch Gen Psychiatry*⁸, Dec 1999, 56, 1073-1086.
- *The MTA Cooperative Group, Moderators and mediators of treatment response for children with Attention-Deficit/Hyperactivity Disorder, *Arch Gen Psychiatry*, Dec 1999, 56, 1088-1096.
- *National Institutes of Health Policy and Guidelines for the Inclusion of Children as Participants in Research Involving Human Subjects, March 6, 1998.
- *National Institutes of Health Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, March 18, 1994.

Pocock S., Clinical Trials. New York: Wiley, 1984, Chapter 8.

- *Powell LH, Unanswered questions in the Ischemic Heart Disease Life Stress Monitoring Program, *Psychosm Med*, 1989, *51*, 479-484.
- *Rosa, Linda, *et al.*, A close look at therapeutic touch. *JAMA*, April 1, 1998, 279 (13), pp. 1005-1010, and Letters to the Editor, *JAMA*, December 9, 1998, 280 (22), 1905-1908
- *Shumaker, SA, *et al.*, Enhancing adherence in randomized controlled trials, *Controlled Trials*, 2000, *21*, 226S-232S
- *Sieber WJ and Kaplan RM, Informed adherence: The need for shared medical decision making, *Controlled Trials*, 2000, 21, 233S-240S

Smith, Marcia Datlow, *et al.*, Facilitated communication: The effects of facilitator knowledge and level of assistance on output. *Journal of Autism and Developmental Disorders*, 1994, *24* (3), 357-367.

_

7/12/2001 Tab 6, Page 3

⁸ Archives of General Psychiatry

Bibliography

Stampfer, M., Obserational epidemiology is the preferred means of evaluating effects of behavioral and lifestyle modification, *Controlled Clinical Trials*, 1997, 18, 494-499.

*Sterling, T. D., *et al.*, Publication decisions revisited: The effect of the outcome of statistical tests on the decision to publish and vice versa, *The American Statistician*, 1995, 49 (1), 108-112.

Task Force of the Working Group on Arrhythmias of the European Society of Cardiology, The early termination of clinical trials: Causes, consequences, and control. *Circulation*, 1994, 89 (6), 2892-2907.

Terrin, M. L., Individual subject random assignment is the preferred means for evaluating behavioral lifestyle modification, *Controlled Clinical Trials*, 1997, 18, 500-505.

Turner, C. F., et al., Adolescent sexual behavior, drug use and violence: Increased reporting with computer survey technology, *Science*, 1998, 280, 867-873.

*Turner, J. A., *et al.*, The importance of placebo effects in pain treatment and research. *JAMA*, 1994, *271*, 1609-1614.

*Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature, Call for comments on a proposal to improve reporting of clinical trials in the biomedical literature, *Annals of Internal Medicine*, 1994, *121* (11), 894-895.

Yusuf, S., et al., Analysis and interpretation of treatment effects in subgroups of patients in randomized clinical trials, JAMA, 1991, 266 (1), 93-99.

Tab 6, Page 4 7/12/2001