

Editorial

NIDCD/VA Hearing Aid Study



The clinical trial is highly valued in the evaluation of new drugs, medical devices, and medical/ surgical treatments. Most simply defined, the “clinical trial” is an experiment conducted with patients that derives its strength from the methodology. A well-designed clinical trial randomly assigns participants into treatment groups and masks or blinds both the participants and investigators regarding group placement. Clinical trials frequently are conducted at multiple sites, each with a local investigator under the guidance of a study chair. Clinical trials often are referred to as the “gold standard” of clinical research design. The evidence generated within the clinical trial is viewed with the strongest credibility regarding a causal relationship between treatment and effect. In fact, such evidence is commonly considered to be definitive regarding the efficacy of a treatment compared to no treatment or placebo, or of a specific treatment relative to others available.

In 2000, Larson and coworkers reported in *The Journal of the American Medical Association* the findings of a clinical trial examining the efficacy of hearing aid use as a treatment for sensorineural hearing loss. The trial was conducted between 1996 and 1998 and was a joint effort between the National Institute on Deafness and Other Communication Disorders and the Department of Veterans Affairs Cooperative Studies Program. It was designed to investigate the relative efficacy of three hearing aid circuits used at that time for limiting the output of hearing aids. The trial employed a double-blind, three-period, three-treatment crossover design. No clinically significant differences between the circuits were reported in the results, but a more compelling finding was observed. The hearing-impaired participants in the trial demonstrated significantly improved aided versus unaided

communication both in quiet *and in noise* on carefully controlled measures of speech intelligibility and on a series of questionnaires regarding hearing aid benefit and satisfaction.

Why were these findings important? Most audiologists in 2000 probably were aware of the efficacy of hearing aids, as reported by Larson et al, from personal experience and from their involvement with the literature. A review of written professional dialogue from the early and mid-1990s reveals, however, that the efficacy of hearing aids as a treatment for sensorineural hearing loss was apparently not as widely accepted as was perhaps thought. Just seven years prior to the Larson report, in a letter dated August 11, 1993, the U.S. Food and Drug Administration formally put the entire hearing aid industry on notice of impending action should the industry persist in the claims made concerning hearing aids “beyond simple amplification.” Of specific concern to the FDA were industry claims of, among others, enhanced speech intelligibility and increased understanding in noise. The letter added that such claims must be supported by clinical data and substantiated by scientific evidence (Kirkwood, 1993).

The Larson et al report helped to establish that validation for short-term hearing aid use during a carefully controlled nine-month clinical trial. One might question, however, the persistence of the positive effects reported by Larson et al over a longer period of time than was encompassed in the trial. In the clinical trial, each participant was enrolled for three months in each of the three treatment conditions, and over the nine-month period, the participants could have been influenced by short-term experimental factors. Consequently, in 2001, a working group convened to design a study to investigate how well the participants in the clinical trial had used

amplification in the years following the completion of their involvement in the trial and if the positive effects associated with amplification had persisted over that period. The five papers that follow in this edition of *JAAA* constitute the findings and conclusions of that follow-up study. The papers have been written in such a way that they build sequentially upon each other and should be read in the order in which they appear. In some instances, the procedures that are reported in the follow-up study were repeated from the original clinical trial; newer instruments, not available at the time of the trial, were also used to describe how these individuals were functioning with their hearing aids. All participants in the follow-up study had been enrolled in the original trial; the pool of follow-up participants constituted nearly two-thirds of the original cohort. The findings of the follow-up study serve as an adjunct to those of the clinical trial and, we trust, strengthen the conclusions drawn by Larson et al concerning the efficacy of hearing aids as an important treatment for sensorineural hearing loss.

REFERENCES

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