



WHAT WE KNOW

AD/HD and Neurofeedback: A Review of Eight Studies

Because neurofeedback is so widely used in the marketplace and many people have questions about its efficacy, the National Resource Center on AD/HD provides the following summaries and critiques of eight major controlled studies dealing with this intervention. This review is provided as a complement to What We Know # 6A: Neurofeedback (EEG Biofeedback) and AD/HD.

Study # 1: Rossiter & LeVaque (1995) compared the clinical effects of 20 half-hour sessions of neurofeedback, 3-5 times per week, to stimulant medication in 46 (23 in each condition) ages 8-21 year-olds diagnosed with ADHD. Patients received the treatment of their (or their parent's) choice and additional counseling and support services. Both groups experienced significant improvements over time on a laboratory-based test of attention. There was no significant difference between treatments.

CRITIQUE: Failure to find a significant difference between treatments in a small unrandomized trial does not prove that neurofeedback is as good as

medication. There might be no difference found because both treatments may have been ineffective in this sample or because the sample happened to be all placebo responders, or because the sample was not large enough. A more definite conclusion might have been reached if one treatment was shown to be significantly better than the other. Even then, the lack of randomization would leave considerable doubt, especially in view of the rather modest pre-post effect sizes. The double design flaw (lack of randomization and lack of untreated control) makes this study's results uninterpretable.

Study # 2: Linden et al (1996) randomly assigned 18 children, aged 5-15, with diagnosed ADHD to a waitlist control condition or 40 sessions of neurofeedback, 45 minutes each. Six (3 in each group) had comorbid learning disorders. Those receiving biofeedback, but not those on the waitlist demonstrated significant improvements in IQ and parent/teacher attention ratings (data not available for effect size of parent and teacher ratings).

CRITIQUE: This study is more convincing than previous studies because of randomization and an untreated control group to control for history, maturation, and statistical regression on scores, with significant difference in results, but it does not control for placebo effect.

Study # 3: Carmody et al. (2001) gave 8 children age 8-10 years not taking medication (4 with ADHD, 4 without) 35-47 sessions of EEG biofeedback in an elementary school setting and compared them to a matched waitlist control group. After 6-months, children in the treatment group had less impulsivity on a laboratory measure of attention and improvements in teacher-rated attention.

CRITIQUE: This study is notable for demonstrating the feasibility of administering neurofeedback in the school setting, which could be of public health importance if the treatment is proven effective. The authors correctly noted that the lack of a placebo group obfuscated whether their results were due to the neurofeedback or attendance at individual sessions away from the classroom, attention of the technician, and/or excitement of a special program. In addition, this design did not incorporate randomization or subject/evaluator blindness and had mixed ADHD and non-ADHD subjects in the treatment group. Therefore it contributes little to determining efficacy of neurofeedback for ADHD, but is of interest for its locus of administration.

Study # 4: Monastra et al (2002) examined a large (N=100) sample of 6-19 years-old with ADHD in an outpatient clinic. All patients received titrated stimulant medication, parent training and counseling, and educational assistance. Neurofeedback was optional and 51 of the 100 chose it (presumably at their own expense, although this was not clear) and received 45-minute, once weekly sessions for 34 to 50 sessions, depending on how long it took them to maintain a certain level of arousal for 45 minutes during 3 consecutive training sessions. After a year, patients were tested with and without their medications. With their medications, both groups showed significant improvement on parent and teacher behavioral ratings, the TOVA and qEEG measures of cortical arousal. After a 1-week medication washout, only the neurofeedback group retained their improvement. Monastra and Monastra (2004) conducted a follow-up of these patients and found differential findings were replicated at 2 and 3 years post-treatment; the quantitative EEG continued to show the changed power spectrum 2 years after treatment ended; and 70% who had received feedback reduced their medication dose by half, whereas 85% of those who did not get feedback had to increase dose.

CRITIQUE: This study has considerable strengths: size of sample, very large and significant effect sizes of group differences in improvement, long-term follow-up, both clinical and neuropsychological measures, and testing the interaction of medication and treatment experience, with a reasonably "hard" outcome measure, the need for further medication, suggesting a complementary effect. The results would have been very impressive and convincing despite lack of blinding if the treatment had been randomized. As it is, the results are only provocative, a naturalistic follow-up, not a real randomized clinical trial. Without randomization, the impressive results could have been mainly or entirely due to those who opted for neurofeedback having a better prognosis anyhow or being more inclined to discontinue medication, or other such factors inherent in the self-selection bias, including family resources to undertake neurofeedback. In fact, a sizable proportion (but not all) of the advantage of neurofeedback was explained by a significant interaction with parental use of consistent reinforcement (Monastra et al, 2002). In-press MTA data (Jensen et al, 2007) presented at the 2005 American Academy of Child Psychiatry meeting show that about half of that sample, especially those more advantaged, had significant improvement to borderline symptom levels at 3 years regardless of whether they continued

treatment. If the ability, willingness, and resources to add neurofeedback to the already comprehensive treatment somehow selected that half of the clinic sample, it could explain the group difference.

Study # 5: Fuchs et al. (2003) compared neurofeedback to stimulant treatment for 34 children age 8-12 with ADHD. Parent preference assigned 22 children to thrice weekly, 30-60 minute, neurofeedback sessions for 12 weeks and 12 children to methylphenidate medication. Neurofeedback was tailored to the child's subtype of ADHD. Both groups showed comparable improvement on behavior ratings and the TOVA.

CRITIQUE: Like Rossiter & LaVaque's (1995) study, these results do not prove there is no difference between neurofeedback and stimulant medication for the same reasons previously stated. Lack of significant difference between groups, lack of randomization, and rather modest pre-post effect size (compared to what one would usually expect from open pre-post effect of stimulant) make the results almost uninterpretable.

Study # 6: Orlandi and Greco (2004) conducted a randomized clinical trial with 36 boys age 9-11 with ADHD combined type without comorbidity or medication. Treatment staff were not blind, but evaluations were done by blinded clinicians and parents were single-blind. Seventeen were randomized to EEG biofeedback and 19 to a control condition of equal duration, frequency, and intensity in the same setting. The control activity was playing a video game that was designed to improve attention, visual tracking, hand-eye coordination, attention to detail, planning, concentration, memory, and patience. Despite the fact that the video-game in the control condition was appealing to children, there was a 41% dropout rate while the biofeedback group only had a 6% dropout rate. The neurofeedback group, but not control group, showed significant improvement by Conners Parent Rating Scale and by independent blinded clinicians Clinical Global Impression-Severity.

CRITIQUE: Although a small sample, this study has the strengths of randomization, convincing control condition, blinding (albeit single-blind) and good characterization of the sample. However, the two treatment groups did not actually separate significantly (a possible power problem) on the critical blinded parent ratings; it was just that biofeedback showed significant improvement and the control improvement failed to reach significance. The failure of the control group to reach significance could also be a power problem with

such a small sample. Therefore the results should be interpreted with caution other than for calculation of effect size.

Study # 7: deBeus et al. (2006) used a double-blind crossover design with 52 children age 7-10 diagnosed with ADHD (50% inattentive type, 50% combined); 46% had comorbid conduct disorder, depression, or anxiety disorders, typical of the ADHD population. All subjects received 20 neurofeedback and 20 sham feedback interventions in randomly assigned order, for a total of 40 treatments. deBeus and colleagues used the neurofeedback technology titled SMART Brain from CyberLearning Technology, LLC. The active treatment was theta suppression with enhancement of SMR or beta; the sham was random rewards from the same equipment. Neurofeedback resulted in significantly better hyperactivity ratings at home and school, attention ratings at home, ability to work with others, organization, study habits, attitude, internalizing symptoms, and computerized tests of attention. During biofeedback a third of the group was able to reduce medication dosage. During biofeedback, but not during sham, the subjects showed the expected power spectrum changes.

CRITIQUE: This appears a respectable study, with randomization, a convincing double-blind sham control, multi-domain assessment, and test of mechanism. Unfortunately, the details have not undergone peer-reviewed publication, and the PI is not willing to share the data necessary for calculation of effect sizes before publication, so the only information available is what was presented at the American Psychiatric Association in May 2006. At this time this study appears impressive, although not compelling without more details.

Study # 8: Finally, Levesque et al. (2006) randomly assigned 20 unmedicated children age 8-12 with ADHD to 40 sessions of neurofeedback (n=15), over 13 ½ weeks (3 sessions per week) or waitlist (n=5). Those receiving neurofeedback, but not those on wait list, improved significantly on a digit span task, the Integrated Visual and Auditory Continuous Performance Task, and parent rating (Conners scale) of inattention and hyperactivity. Importantly, fMRI activation of the right anterior cingulate, left caudate, and lateral prefrontal cortex was found only in those who had neurofeedback.

CRITIQUE: Although a small sample, this study is interesting because it demonstrated differential neurofeedback activation of brain areas reported to be smaller or hypoactive in ADHD by numerous reputable

investigators. Unfortunately, there was no sham treatment to control for placebo effect, but it seems unlikely (though possible) that placebo effect would activate those particular brain areas in all those receiving biofeedback. It is also notable that this study used thrice-weekly treatment in contrast to most previous studies, which used twice weekly treatment.

SUMMARY

In summary, four of the eight controlled studies conducted to date were randomized, but two of these used a wait list as the control. Although wait list is often used in behavioral treatment studies, those studies often use other techniques, such as multiple baseline and reversal designs, to compensate somewhat. This leaves 2 small blinded randomized studies (Orlandi & Greco, 2004; deBeus et al., 2006) with a credible control condition. Neither of these have yet undergone peer-reviewed publication. The deBeus trial is reasonably impressive although details are not yet available, and taken together with the flawed published studies, suggests a moderate effect in at least some patients. Of public health importance, one of the studies (Carmody et al, 2001) suggests it may be feasible to administer treatments in schools. In fact, Foks (2005) reported that over the last decade several schools in the USA have begun to utilize neurofeedback for the special education of children with ADHD and learning disorders, with corresponding increases in regular class inclusion and significant financial savings.

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