

# Neurofeedback is the Best Available First-Line Treatment for ADHD: What is the Evidence for this Claim?

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Attention Deficit/Hyperactivity Disorder (ADHD) is a chronic syndrome characterized by deficits in executive functions and attentional processes. Persons diagnosed with ADHD have significant deficits in self-regulation evidenced by difficulty staying focused, controlling impulsive behaviors, and for many, restraining hyperactive motor activity. These symptoms typically create problems in academic, social, and familial contexts as well as in the planning and organization skills needed for daily functioning. Additionally, comorbid syndromes that can mimic the symptoms of ADHD and confound differential diagnosis are commonly present (e.g., anxiety, depression, learning disorders).

ADHD is the most frequently diagnosed pediatric disorder with 11% of American school-aged children (and nearly 20% of teenage boys) having been medically diagnosed with ADHD according to the latest report from the Centers for Disease Control (Schwarz & Cohen, 2013). Stimulant medication (SM) and behavior therapy (BT) are the two most widely accepted treatments for ADHD, with approximately 70% of those diagnosed prescribed medication (Schwarz, 2013). Although both interventions are considered to meet the highest standards for the evidence-based treatment of ADHD, and have been recognized as such by the American Academy of Child and Adolescent Psychiatry (AACAP) and Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD), the leading ADHD advocacy group, the actual evidence is that these treatments fail to result in sustained benefit for the vast majority of children who receive them and, therefore, do not warrant being the first option for treating ADHD.

# The Evidence Against Stimulant Medication and Behavior Therapy as First-Line Treatments

The evidence against SM and BT comes primarily from two large NIMH-funded ADHD studies that included long-term follow-up assessments. The first was the Multimodal Treatment of ADHD (MTA) Cooperative study, the gold standard study in ADHD treatment effectiveness research costing \$21 million in taxpayer funding. The MTA trial was a cooperative study designed and overseen by America's foremost experts in SM and BT treatments for ADHD. This study randomly assigned 579 ADHD children to receive either systematic stimulant medication management (SSMM), multi-component BT, combined SSMM/BT, or simply an assessment and referral to community care (CC) in which the referred children/families may or may not have actually received treatment services (MTA Cooperative Group, 1999). The children that received SSMM, BT, or combined SSMM/BT were then referred to community professionals for ongoing care at the end of their 14 months of study-directed treatment. Follow-up assessments were then conducted at 10 months

(MTA Cooperative Group, 2004a, 2004b), 22 months (Jensen et al., 2007), and 4.83 and 6.83 years (Molina et al., 2009) after the end of study-directed treatment. The MTA authors took a "spare-no-expense" approach in designing each intervention to ensure that the children received optimal versions of the assigned care (Pigott et al., 2013). Table 1 describes each treatment condition. As detailed in Table 1, our cost estimate in today's dollars for the 14 months of SSMM is \$5,310, \$15,250 for BT, and \$21,560 for the integrated SSMM/BT treatment.

The MTA trial was an open-label study and relied primarily on non-blinded parent and teacher rating scales to evaluate outcomes with these raters systematically involved in the delivery of BT, SSMM, and combined SSMM/BT treatments (but not CC), thereby biasing the reports of outcomes based on these measures when compared to CC (Hammond, 2011). The 14 months of BT failed to demonstrate better outcomes on the non-blinded measures than CC, and combined SSMM/BT failed to separate from SSMM alone. We were surprised to discover, though, that CC was actually found to be superior to BT on the blinded measure of ADHD classroom behaviors contrary to the widely reported equivalence in BT and CC outcomes (see Table 4; MTA Cooperative Group, 1999).

The lack of separation between SSMM and combined SSMM/BT on the non-blinded ratings presents difficulty in concluding that 14 months of BT in children's homes and classrooms provided any advantage over SSMM alone in treating ADHD. Furthermore, the fact that the children referred to the randomness of community/hodgepodge care improved substantially more on the blinded measure of ADHD than those who received BT adds new evidence to the conclusion that 14 months of "spare-no-expense" BT had only a small beneficial effect.

This conclusion regarding BT's relative ineffectiveness is supported further by Hodgson et al.'s (2012) meta-analytic finding that behavior modification, school-based behavior therapy, behaviorally-based parent training, and behavioral self-monitoring treatments each had negative effect sizes compared to the control group conditions prompting the authors to conclude that these four commonly-utilized BT treatments for ADHD "cannot be deemed to be efficacious." Similarly, Sonuga-Barke et al.'s 2013 meta-analysis published in the American Journal of Psychiatry found that BT had a non-significant effect size of only .02; demonstrating again that BT has, at best, only a minuscule benefit for the ADHD children receiving it. Consequently, BT should be disqualified as a first-line treatment based on both the MTA study findings and these two meta-analyses since BT is simply not reliably helpful no matter its components nor how optimally they are administered.

As for stimulant medication, while both SSMM and SSMM/BT separated from CC on the non-blinded parent and teacher ratings at the end of study-directed treatment, once again the blinded measures tell a different story. These blinded measures found equivalent improvements in ADHD and aggression/oppositional defiance disorder (ODD) behaviors for the CC group contrary to the widely reported superiority of SSMM and combined SSMM/BT (see Table 4; MTA Cooperative Group, 1999). The MTA authors' failure to elucidate this lack of separation on the blinded measures presents significant deficiencies in their conclusions drawn from the study. While the authors asserted the superiority of SSMM, stating in their main article's abstract that "study medication strategies were superior to community care treatments," the blinded assessments clearly do not support this claim.

To date, the findings from the blinded measures, and the implications thereof, have not been addressed by the authors, or to our knowledge, any article referencing this study. Instead, it is commonly cited that SSMM is superior to the randomness of community/hodgepodge care

referencing the MTA study to support this claim. For instance, the AACAP's ADHD Treatment Guideline states, "Children in the MTA who were treated in the community with care as usual from whomever they chose or to whom they had access received lower doses of stimulants with less frequent monitoring and *had less optimal results*" (emphasis added; AACAP, 2011). Yet this AACAP claim was only true for the biased non-blinded ratings in which both parents and teachers were deeply involved for 14 months in the delivery of SSMM care (see Table 1).

Table 1

Descriptions of the MTA Cooperative Study Treatments

#### Systematic Medication Management

Children had an initial 28-day, double-blind, daily switch titration of methylphenidate, using 5 randomly ordered repeats each of placebo, 5mg, 10 mg, and 15 or 20 mg at breakfast and lunch with a half afternoon dose. Expert clinicians blindly reviewed graphs of daily-administered parent and teacher ratings of the child's responses to each of the three doses and placebo and by consensus selected his/her best dose. The agreed-on dose (if not placebo) became the child's initial dose. This procedure was followed to optimize symptom reduction while minimizing adverse side effects for each child.

For children not obtaining an adequate response during titration, the pharmacotherapist performed non-blinded trials of 3 or more additional medications, and evaluated the effectiveness of each of these trials based again on parent and teacher ratings of the child's responses to same.

The pharmacotherapist met monthly for a half-hour office visit with parents to review concerns, evaluate progress, and recommend readings.

The pharmacotherapist communicated monthly by phone with the child's teachers and readjusted medications if the child was not doing well.

Cost Estimate: Selection of optimal dose \$1,000

13 half-hour office visits x \$120 per visit = \$1,560 13 teacher phone calls x \$50 per call = \$650

14 months of medication x \$150 per month = \$2,100

Total Cost Estimate: \$1,000+\$1,560+\$650+\$2,100 = \$5,310.00

Multi-Component Behavior Therapy **Parent Training:** Parents attended 27 group and 8 individual sessions for parent training. **Cost Estimate:** 27 group sessions x \$70 per group = \$1,890

8 individual sessions x \$140 per session = \$1,120

**Child-Focused Treatment:** Children attended an 8-week, 5-days-per-week, 9-hours per-day summer camp providing intensive behavioral interventions supervised by the same teacher-consultants who performed parent training and teacher consultation. Behavioral interventions were delivered in group-based recreational settings, and included a point system tied to specific rewards, time out, social reinforcement, modeling, group problem-solving, sports skills, and social skills training. The summer program included classrooms for individualized academic skills practice and reinforcement of appropriate behavior.

Cost Estimate: \$500 per week x 8 weeks = \$4,000

**School-Based Treatment:** School-based treatment had 2 components: 10 to 16 sessions of biweekly teacher consultation focused on behavior management and 12 weeks (60 school days) of a part-time, behaviorally trained, paraprofessional aide working directly with the child. The aides had been counselors in the summer camp, and the program continued in the fall, to help generalize treatment gains made in the camp into the classroom. Throughout the school year, a daily report card linked home and school. The daily report card was a 1-page teacher-completed checklist of the child's successes on specific preselected behaviors, and was brought home daily by the child to be reinforced by the parent with home-based rewards.

**Cost Estimate:** 16 teacher consultation sessions x \$140 per session = \$2,240 60 days of in-school aide x \$100 per day = \$6,000

Total Cost Estimate for BT: \$1,890+\$1,120+\$4,000+\$2,240+\$6,000 = \$15,250.00

Combined	
SSMM and	RT

Combined SSMM/BT treatment provided all of the treatment components outlined above in an integrated manner. Information was regularly shared between the behavioral psychologist/teacher-consultant and pharmacotherapist. Manualized guidelines determined if and when an adjustment in one treatment should be made versus first intervening with the other.

Cost Estimate: Information sharing and ongoing psychologist/pharmacotherapist

consultations \$1,000.00

Total Cost Estimate: \$1,000+\$5,310+\$15,250 = \$21,560.00

Additional Tx

The groups were authorized up to 8 additional sessions as needed. At the end of study-directed treatment, children/families were referred to CC.

Referral to CC

Children/parents assigned to CC were provided an assessment report and list of CC providers. The parents may or may not have followed through with treatment referrals. Two-thirds of the CC children received ADHD medications from their own provider during at least part of the 14 months.

Note. (Adapted from Pigott et al., 2013)

Interestingly, the initial superiority of SSMM and SSMM/BT over CC on the non-blinded measures was cut in half at the 10-month follow-up assessment and disappeared entirely in all subsequent assessments. The most parsimonious interpretation for this dramatic loss of separation over time is that they were foretold by the absence of separation in the initial blinded assessments. In other words, as parents and teachers became "less proximal" to their roles in delivering the SSMM and SSMM/BT children's treatment due to the passage of time, their ratings became less biased, thereby eliminating the initial appearance of added benefit from these high-cost treatments.

Fourteen years after publishing the MTA study's initial findings, many of its authors confessed regrets for overselling the value of SSMM in a New York Times (NYT) article titled, "ADHD Experts Re-evaluate Study's Zeal for Drugs" (Schwarz, 2013). Unfortunately, these researchers' regrets focused on underselling the value of BT and combined SSMM/BT relative to SSMM alone, not their selective reporting of study outcomes. Their NYT regrets are not supported by their own blinded measures, since comprehensive and optimally-administered BT did substantially worse than CC, and neither SSMM alone nor when combined with BT separated from "refer-and-forget" care.

What the Cooperative should regret is not exploring in detail the negative findings from the blinded measures back in 1999. Instead, these negative findings were buried on the second page of a table, leaving them to languish in obscurity versus compelling the search for more effective treatments that might be different from these experts' preferred ones. Perhaps the best indicator of the dismal impact from the MTA study's high-cost treatments is the fact that during follow-up 10.4 to 12.3% of the BT, SSMM, and integrated SSMM/BT treated children had one or more psychiatric hospitalizations compared to only 8.3% for the CC group, and many of the CC children received little-to-no actual treatment for their ADHD; certainly not the 14 months of optimized high-cost treatments the other children received (Molina et al., 2009).

More troubling still, in the 22-month follow-up assessment it was found that "**medication use** was a significant marker, not of beneficial outcome, but of deterioration" (Jensen et al., 2007), and similarly, in the last follow-up assessment they found that SM use "was associated with worse hyperactivity-impulsivity and ODD symptoms and CIS [Columbia Impairment Scale] impairment" (emphasis added; Molina et al., 2009).

It is unclear if these correlations between SM and deteriorating outcomes were causal (i.e., while initially helpful, continued SM became iatrogenic overtime as children habituated to their performance enhancing effects and then continued SM worsened outcomes across multiple dimensions), as it may only reflect that those ADHD children doing worse were taking SM because they were worse. *These findings do indicate, though, that continued SM provided at best only a marginal and depreciating benefit, and perhaps significant harm, to struggling children.* Regarding sustained effectiveness, even the authors acknowledge, "although the MTA data provided strong support for the acute reduction of symptoms with intensive medication management, these long-term follow-up data fail to provide support for long-term advantage of (continued) medication treatment beyond 2 years for the majority of children" (Molina et al., 2009). Left unexplored by Molina et al. is the likelihood of harm from ongoing SM treatment.

The second NIMH-funded trial is the Preschool Attention-Deficit/Hyperactivity Disorder Treatment Study (PATS). This study was a multisite, randomized trial evaluating the short-term efficacy of SM in preschoolers, aged 3.0 to 5.5 years, with ADHD (Combined or Predominantly Hyperactive/Impulsive Type) in the moderate-to-severe range. PATS enrolled 304 children and their caregivers, of which 261 completed the opening 10-weeks of parent training, 169 completed open-label lead-in of SM, 147completed the double-blind SM phase comparing various dosing levels of SM to placebo, and 140 enrolled in the open-label SM maintenance phase. The main finding from this stage of the study was that only 21% of the preschoolers achieved remission from ADHD on the best-dose SM while even 13% achieved remission on placebo (Greenhill et al., 2006).

In 2013, Riddle et al. followed up on 207 of the 261 preschoolers whose caregivers completed parent training, re-evaluating them at years 3 (mean age 7.4), 4 (8.3), and 6 (10.4). This study found that "*medication status during follow-up, on versus off, did not predict symptom severity*" and despite parent training and systematic SM at the study's outset, the authors concluded:

ADHD in preschoolers is a relatively stable diagnosis over a 6-year period. The course is generally chronic, with high symptom severity and impairment, in very young children with moderate-to-severe ADHD, *despite treatment with medication*. Development of more effective ADHD intervention strategies is needed for this age group.

#### Furthermore,

In this 6-year follow-up study, almost 90% of clinic-referred preschoolers initially diagnosed with *moderate-to-severe ADHD*, who mostly received parent training followed by controlled medication treatment, continued to be diagnosed with ADHD in to mid-to-late childhood. *Across the sample, severity of symptoms, despite initial decline, remained primarily in the moderate-to-severe clinical range* (emphases added; Riddle et al., 2013).

Interestingly, the PATS researchers also reported "medication treatment in the original PATS predicted HIGHER ADHD symptom severity between follow-up years 3 and 6 in some, but not all, models;" raising again the issue identified in the MTA study of the likelihood of harm resulting from continued SM treatment. More troubling still, by year 3 (age 7), an antipsychotic had been added to 8.3% of the preschoolers' medication regimen (and for 10.7%, a norepinephrine reuptake inhibitor), and by age 10, 12.9% were taking an antipsychotic (and for 8.6%, an SSRI), suggesting that stimulant medications act as gateway drugs to psychiatric drug cocktails for many ADHD children.

This repeated pattern in the MTA and PATS studies of the loss of efficacy in ADHD medications likely accounts for the dramatic increase in the prescribing of antipsychotics to children, as it mirrors the dramatic increased diagnosis of ADHD and prescribing of stimulants to them. In a 2012 article published in *Archives of General Psychiatry*, Olfson et al. report that between 1993-1998 and 2005-2009, the rate of antipsychotics prescribed to children increased by over 750%. Their analysis found that disruptive behavior disorders (primarily ADHD) were the most common diagnoses in children that were prescribed an antipsychotic, accounting for 63% of such cases, and that in *54.1%* of the outpatient visits, *whenever an antipsychotic was prescribed, there was also an ADHD medication prescribed to the same child*. A similar pattern of dramatic increased prescribing of various psychiatric medications to children/teenagers has occurred (Olfson et al., 2014), adding further evidence that stimulant medications act as gateway drugs to more psychiatric drugs in the often fruitless pursuit of a chemical cure for many ADHD children whose parents initially choose this course of care.

It is troubling to read NIMH's conclusions drawn from the PATS study. The press release accurately notes that after six years there was high symptom severity and impairment for these children with 89% still meeting the diagnostic criteria for ADHD regardless of whether they were on or off medication during follow-up. Despite the clear implications from these findings, and those from the MTA study, for the need to dedicate research dollars into investigating alternatives to ADHD medications, the press release's "What's Next" section states, "In an effort to improve outcomes for these children, more research is needed on the effects of ADHD medications on preschoolers over the long term, as well as the effects of combining different medications" (emphasis added, NIMH website). It is unclear if this press release just reflects the overzealous musings of an NIMH public relations' employee or is reflective of NIMH's leadership. Either way, it is clearly an inappropriate use of taxpayers' money to experiment on the effects of powerful psychiatric drug cocktails on preschoolers' developing brains in search of a chemical cure, as such proposed research is ethically dubious and would likely result in far more harm than good.

Stimulant medications have clear short-term effectiveness in treating ADHD for many children, which is why they are tested for, and banned, as performance enhancing drugs in most professional, national, and international sporting events. Similar to most psychiatric medications, even when initially helpful, stimulant medications commonly lose efficacy over time due to habituation and for many become deleterious. In 2009, NIMH Director Dr. Thomas Insel noted, "The unfortunate reality is that current medications help too few people to get better and very few people to get welf" (Insel, 2009). Dr. Insel's cogent observation certainly applies to the use of stimulants to treat ADHD. When the documented adverse effects of stimulants on ADHD children's growth, neural functioning, and cardiovascular system (Graham et al., 2011) are combined with their lack of demonstrated long-term efficacy and gateway effect to other psychiatric drugs, stimulant medications must be displaced from their current status as the first-line treatment for ADHD.

#### The Evidence for Neurofeedback as First-Line Treatment for ADHD

Neurofeedback (NFB) is a form of BT with more than 50 years of basic and applied research combining real-time feedback of brain activity with the scientifically-established principles of operant conditioning to teach trainees how to self-regulate targeted aspects of brain functioning. As such, NFB is uniquely suited to treat ADHD children provided that 1) the child's symptoms are functionally related to the targeted brain activity, and 2) the child learns to self-regulate this activity.

In the 1960s, neuroscientists demonstrated that decreases in the motor activity of cats was associated with increased 12–16 Hz neuronal electrical activity in the sensorimotor cortex, an activity pattern Professor Sterman named the sensorimotor rhythm (SMR). Sterman and his colleagues found that when hungry cats were fed droplets of milk contingent upon the increase in SMR activity, the cats "became very alert" and displayed "an almost intense cessation of movement" (Sterman & Wyrwicka, 1967)—the essential behavioral deficits found in children with ADHD. In the 1970s, using a scientifically rigorous within-subject reversal design with blinded raters to treat four ADHD boys, Lubar and Shouse published the first controlled studies demonstrating a specific effect for NFB in reducing the core symptoms of ADHD (Lubar & Shouse, 1976; Shouse & Lubar, 1979). They found that when the ADHD boys were reinforced for increasing SMR, their hyperactive and distractible/inattentive symptoms significantly decreased, and these treatment gains were reversed when the boys were reinforced for decreasing SMR.

Building on the foundation provided by Professors Sterman, Lubar, and Shouse, NFB's evidence-base has grown to more than 60 published studies that find it effective in treating ADHD's core symptoms. The vast majority of these studies used either standardized EEG frequency-based protocols such as SMR training and increasing the theta/beta ratio (TBR) or slow cortical potential (SCP) training based on research demonstrating that trainees can learn to self-regulate the amplitude of a negative shift in slow-wave activity in anticipation of an expected event such as waiting for a timed test to start. A 2009 meta-analysis found NFB using these standardized protocols is efficacious and specific with large effect sizes (ES) for inattention and impulsivity and medium ES for hyperactivity (Arns et al., 2009). In 2012, the organization that maintains the American Academy of Pediatrics' ranking of evidence for psychosocial treatments awarded NFB the highest level of scientific support for treating ADHD (PracticeWise, 2012). More recently, Arns et al. (2014) published a meta-analysis of randomized trials comparing the standardized NFB protocols to semi-active (e.g., EMG biofeedback) and active (e.g., computerized cognitive training) treatment control group conditions. This analysis found that NFB demonstrated specificity and at least a medium ES in treating ADHD's core symptoms compared to these semi/fully active treatments.

Table 2 is a detailed review of 16 controlled studies published since 2000 that evaluated NFB's effectiveness in treating the core symptoms of ADHD. Summarizing across these studies (combined N = 828), our review found that, in comparison to control group conditions, NFB resulted in significant improvements in:

- Parent-rated core symptoms of ADHD (15 studies);
- Teacher-rated core symptoms of ADHD (12 studies);
- Computerized continuous performance tests of core ADHD symptoms (8 studies);
- Neuropsychological measures of response inhibition, reaction time, and concentration (4 studies); and

Neurophysiologic measures of improvement relevant to ADHD, including the QEEG Attention Index (1 study), Event-Related Potentials (P300) during continuous performance testing (1 study), and activation of regions in the brain related to attention and executive functioning using fMRI (1 study).

Table 2

Controlled Neurofeedback Studies in Treating ADHD

Study	Subjects/Design	Key Findings
Carmondy et al., 2001	16 children ages 8-10, 8 with and 8 without ADHD. Children were randomly assigned to 2 groups of 4 matched pairs. The 1st group (4 with & 4 without ADHD) received 36 - 48 NFB training sessions at school. The 2nd group served as a wait-list control group. All children were unmedicated. Outcome measures included teacher-completed ADDES and the TOVA. All measures were administered before NFB training, at the midpoint, and after training.	<ol> <li>Only the children with ADHD that were trained with NFB had significantly reduced hyperactivity/ impulsivity as assessed by the TOVA.</li> <li>Significant TOVA improvements occurred on the Commission Errors (p &lt; .01) and Anticipatory Scores (p &lt; .03) Scales.</li> <li>Due to study design, TOVA results cannot be attributed to maturation, time of year, repeated testing, or the training setting/experience.</li> <li>Teachers' ratings on the ADDES Inattention scale were significantly (p &lt; .002) improved for the NFB group.</li> </ol>
Monastra, Monastra, & George, 2002 Long-term follow-up study described in Monastra, 2005	100 ADHD children and adolescents ages 6-19 who demonstrated cortical EEG slowing from a central site. 51 subjects received an average of 43 NFB sessions, 49 did not. All patients received stimulant medication & academic support at school (IEP/504 plan with school accommodations), and their parents received a 10-week parenting program. Outcome measures were the Home & School versions of the ADDES, the TOVA, parenting style, and QEEG Attention Index. All pretreatment measures were administered when patients were unmedicated. Post-treatment measures were later while medicated, 1 week after off medication, and 3 years after the initial evaluation.	1) Only NFB training resulted in significant improvements on behavioral, TOVA, and QEEG Attention Index measures when medications were withdrawn.  2) On the ADDES, parent & teacher ratings revealed significant (p < .001) improvements in hyperactive/impulsive & inattentive behaviors post-training, 1-week after medications were withdrawn.  3) Post NFB training, all TOVA scales were improved to the unimpaired range when measured 1 week after medication withdrawal.  4) Post NFB training, the QEEG Attention Index dropped into the normal range when measured 1 week after medication withdrawal.  5) 3-year follow-up after initial evaluation revealed that the NFB group alone sustained gains on all measures while unmedicated, and 80% of the NFB group had reduced their medications by 50% or more.  6) None of the children who did not receive NFB had been able to reduce their dosage of stimulant medication in the follow-up assessment, and 85% had increased their dosage.

### Fuchs et al., 2003

34 ADHD children ages 8-12 were assigned based on parental preference to NFB (n = 22) or stimulant medication (n = 12). NFB consisted of 30 60-min sessions with sessions administered 3x's per week. The NFB protocol was either theta/beta or SMR training dependent the child's subtype of ADHD. The doses for the medication group were adjusted during study based on need and ranged between 10 and 60 mg/day. Outcome measures were the TOVA, Attention Endurance Test, parent & teacher rated CBRS, and the WISC.

- 1) Both groups showed significant improvement in each of the outcome measures with no significant differences between groups.
- 2) The authors conclude "These findings suggest that neurofeedback was efficient in improving some of the behavioral concomitants of ADHD in children whose parents favored a nonpharmacological treatment"

#### Heinrich et al., 2004

**22 ADHD children** ages 7-13 were assigned to NFB (n = 13) and a wait-list control group (n = 9). The NFB children received 25 SCP training sessions over the course of 3 weeks. Starting at week 2, the NFB children were instructed to practice their strategies at home. **Outcome measures** were the parent rated FBB-HKS, CPT, and event-related potential (P300) during CPT.

- 1) SCP training resulted in significant reductions in core ADHD symptoms as rated by parents.
- 2) SCP training resulted in significant improvements in the more objective laboratory measures compared to those children in the wait-list control group.
- 3) The authors concluded that "this study provides first evidence for both positive behavioral and specific neurophysiological effects of SCP training in children with ADHD."

#### Rossiter, 2004

62 ADHD children and adults ages 7-55 were matched to NFB (n = 31) or stimulant medication (n = 31) based on patient or parent preference. Patients were matched by (in order) age, sum of 4 baseline TOVA scores, IQ, gender, and ADHD subtype. The medication patients were titrated based on TOVA results and maintained on the dose that maximized TOVA scores. The NFB patients received either 40 sessions in office or 60 at home over 3-3.5 months. Outcome measures were the TOVA for both groups and for the NFB group only either a child or adult ADHD rating scale.

- 1) Both the NFB and stimulant medication groups had similar significant improvements in attention, impulsivity, and processing speed on the TOVA with no significant differences between groups.
- 2) The NFB group demonstrated statistically and clinically significant improvement on behavioral measures (Behavior Assessment System for Children, ES = 1.16, and Brown Attention Deficit Disorder Scales, ES = 1.59).
- 3) The author concluded that "confidence interval and nonequivalence null hypothesis testing confirmed that the neurofeedback program produced patient outcomes equivalent to those obtained with stimulant drugs."

scales.

deBeus, 2006; deBeuss & Kaiser, 2011 53 ADHD children ages 7-11 were randomly assigned in a cross-over design to first receive either 20 30-minute theta/beta NFB sessions or 20 sham NFB sessions. After these sessions, the children who had received active NFB received 20 sham sessions & those who had received sham NFB received 20 sessions of theta/beta NFB. Children were assessed after each block of 20 sessions. Outcome measures included the IVA, parentrated CPRS, and teacher-rated CTRS.

NFB was superior to sham feedback on the IVA's response control and attention scales, on the CPRS's inattentive scale, and the CTRS's inattentive & hyperactive-impulsive scales.
 Of the 42 children who completed all 40 sessions, 31 were classified as NFB-learners because their theta/beta EEG ratio improved in the desired direction by one-half a standard deviation or more following active NFB and 11 were classified as NFB non-learners.
 NFB-learners were superior to non-learners on the IVA's response control and attention scales and the CTRS's inattentive.

hyperactive-impulsive, and ADHD total score

Levesque et al., 2006

20 ADHD children ages 8-12 were randomly assigned on a 3:1 ratio basis. The 15 NFB children received 40 sessions of theta/beta training while 5 children were waitlisted.

Outcome measures included pre/post changes in fMRI, Digit Span subtest of the WISC, IVA, CPRS Inattention and hyperactivity scales, Counting Stroop and Go/No-Go Tasks.

- 1) On the fMRI, NFB resulted in significant activation of the right anterior cingulate cortex (ACC), right ventrolateral prefrontal cortex, right dorsal ACC, left caudate nucleus, and left substantia nigra, whereas no significant changes were seen in the control group.
- 2) NFB was superior on each of the other outcome measures.
- 3) The authors concluded that NFB "has the capacity to functionally normalize the brain systems mediating selective attention and response inhibition."

Strehl et al., 2006 25 ADHD children ages 8-13 received 30 SCP NFB sessions lasting 60 minutes in 3 phases of 10 sessions each. Transfer trials without SCP feedback were intermixed with feedback trials to foster generalization of treatment effects. In addition to the NFB sessions, in the third phase children practiced their SCP self-regulation strategy during homework. Outcome measures included parent and teacher ratings of ADHD symptoms (DSM questionnaire for ADHD; Eyberg Child Behavior Inventory; CPRS, and CTRS), IQ (WISC), and a computerized measure of attention.

- 1) Children with ADHD can learn to regulate slow negative cortical potentials.
- Children's ability to successfully produce SCP shifts in trials without feedback had better clinical outcomes than those children who were less successful.
- 3) Parents and teachers reported significant behavioral and cognitive improvements for the children following SCP training.
- **4)** After SCP training, significant improvements in attention and performance IQ score were also observed.
- 5) The positive changes in parent and teachers ratings, attention, and IQ continued when reassessed 6 months after SCP treatment ended.

While this is was not a controlled study, it was included because of its report of 6-month follow-up results and correlating the children's improvement in learning to regulate SCP and to having better clinical outcomes.

Drechsler et al., 2007

30 ADHD children ages 7-13 were randomized to NFB (n = 17) and a group for cognitive behavioral training CBT (n = 13). CBT groups had 15 90-min sessions. The NFB group had 30 45-minute SCP training sessions twice per day for 2 weeks, followed by a 5-week break, then 5 double sessions, once or twice per week for 3 weeks. Parents and children were taught how to practice generalizing SCP activation/deactivation to real life situations. Outcome measures included parent and teacher rated ADHD symptoms (FBB-HKS, CPRS, CTRS, BRIEF), neuropsychological measures for alertness, inhibitory control, selective attention, sustained attention, and switching attention using the TAP and subtest scores from TEA-ch. Learning cortical self-regulation was evaluated by computing the difference between activation during sessions 2 and 3 vs. 13 and 14.

- 1) NFB was superior to CBT in the parent and teacher ratings, particularly in the attention and cognition-related domains.
- 2) Children in both groups showed similar improvement on the neuropsychological measures, however only about half of the NFB group learned to regulate cortical activation during the transfer condition without direct feedback. Behavioral improvements of this subgroup were moderately related to NFB training performance, whereas effective parental support better accounted for some advantages of NFB training compared to CBT group therapy according to parents' and teachers' ratings
- 3) The authors concluded that "there is a specific training effect of neurofeedback of slow cortical potentials due to enhanced cortical control. However, non-specific factors, such as parental support, may also contribute to the positive behavioral effects induced by the neurofeedback training."

Leins et al., 2007

Gani et al., 2008 for 2-year follow-up 38 ADHD children ages 7-13 were matched by age, sex, IQ, dx, and medication status and then randomly assigned either theta/beta NFB (n = 19) or SCP NFB (n = 19). NFB training consisted of 30 60-minute sessions. For both groups, 23% of the NFB sessions were spent on transfer trials in which the subjects attempted to activate the targeted EEG via self-regulation only without real-time feedback and only learned if they were successful after the end of the transfer trial. Both groups also were taught transfer exercises to practice at home to use their self-regulation strategies for EEG activation in everyday life situations. Three booster sessions were also administered as part of the 6-month and 2-year follow-up assessments and used to calculate EEG selfregulation skills. Outcome measures included parent and teacher ratings of ADHD symptoms (DSM questionnaire for ADHD. Evberg Child Behavior Inventory. CPRS, and CTRS), IQ (WISC), and for the SCP NFB group, SCP

- 1) Both NFB groups learned how to intentionally regulate cortical activity consistent with their training and significantly improved in attention and IO
- 2) Parents and teachers reported significant behavioral and cognitive improvements for the children in both NFB groups.
- 3) The NFB groups did not differ in behavioral or cognitive outcomes.
- 4) The clinical effects for both NFB groups remained stable six months after treatment termination.
- 5) In the 2-year follow-up, all improvements in behavior and attention that had been observed at previous assessments remained stable with further significant reductions in the number of reported problems and significant improvement in attention.
- 6) EEG-self regulation skills were maintained for the children in both groups when reassessed 2 years after NFB treatment ended.
  7) In each NFB group, half of the children no longer met the criteria for ADHD, and only 22% were talking medication for ADHD.
- 8) The authors concluded that, "neurofeedback appears to be an alternative or complement to traditional treatments. The stability of changes might be explained by normalizing of brain functions that are responsible for inhibitory control, impulsivity and hyperactivity."

amplitude during activation and deactivation tasks; and for the theta/beta group the theta/beta ratio during activation and deactivation tasks.

Holtmann et al., 2009

34 ADHD children, ages 7 to 12, were randomly assigned on a 3:2 ratio basis to receive either 20 theta/beta NFB sessions (n = 20) or 20 sessions of Captain's Log (n =14), a cognitive training software program. All children also received a 2-week intensive behavioral day clinic, weekly parent training, and 79% were on medication for their ADHD. Outcome measures included pre/post change on Stop-Signal test, a neurophysiologic measure of response inhibition (Go/NoGo-N2), and the parent-rated SNAP-IV.

- 1) Only NFB resulted in normalization of a key neurophysiologic correlates of response inhibition.
- **2)** Only NFB resulted in a significant reduction in impulsivity errors on the Stop-Signal test.
- 3) There were no differential effects on parent ratings.
- 4) The combination of both groups receiving intensive all-day behavior therapy and 79% of the children being on medication may have attenuated the ability to show differences between treatment groups on the parent ratings.

Gevensleben et al., 2009a, 2009b; Wangler et al., 2011;

Gevensleben et al., 2010 for 6-month followup 102 ADHD children, ages 8 to 12, were randomly assigned on a 3:2 ratio basis to receive either 36 sessions of NFB or 36 sessions of Skillies, an award-winning German cognitive training software program. The 62 NFB children were further randomized to receive first either a block of 18 theta/beta training sessions OR 18 slow cortical potential (SCP) training sessions and to switch protocols for the second block of 18 NFB sessions. Outcome measures were German rating scales (FBB-HKS and FBB-SSV) blindly administered to teachers and parents at baseline, after 18, and after 36 sessions. Pre/Post changes in EEG were assessed along with 6-month followup data for the two-thirds of children who had not dropped out or started some other treatment.

- 1) Only NFB produced significant changes in EEG, and these changes were specific to each form of NFB training and furthermore, were associated with improvements on the ADHD rating scales.
- 2) On the parent and teacher rating scales, improvements in the NFB group were superior to the Skillies group for reducing:
- Overall ADHD symptoms (p < .005 & p < .01, both respectively)
- Inattention (p < .005 & p < .05, both respectively)
- Hyperactivity/Impulsivity (p < .05 & p < .1, both respectively)
- Oppositional Behavior (p < .05, parent rating only) Delinquent & Physical Aggression (p < .05, parent rating only).
- 3) No significant differences in effects were found between the two NFB protocols (theta/beta training & SCP training).
- 4) Overall, at the 6-month follow-up the NFB group continued their improvements compared to the Skillies group.
  5) Finally, as only 50% of the NFB group was classified as treatment responders, the authors concluded that "though treatment effects appear to be limited, the results confirm the notion that NFB is a clinically efficacious module in the treatment of children with ADHD."

## Bakhshayesh et al., 2011

**35 ADHD children**, ages 6 to 14, were randomly assigned to receive either 30 theta/beta NFB sessions (*n* = 18) or 30 sessions of electromyography (EMG) biofeedback (*n* = 17). Single-blinded RCT. **Outcome measures** included pre/post change on parent and teacher ratings using the FBB-HKS; CPT, the bp and d2 attention tests, and changes in the theta/beta ratio and EMG amplitude.

- 1) Training effectively reduced theta/beta ratios and EMG levels in the NF and BF groups, respectively.
- 2) Compared to EMG biofeedback, NFB significantly reduced inattention symptoms on the parent rating scale and reaction time and concentration on the neuropsychological measures.
- **3)** While children in both groups made significant improvements on most measures thereby making it difficult with such a small *N* for NFB to separate from EMG biofeedback, in ALL 11 outcome measures (and subscales thereof), the level of improvement was greater for NFB, and a non-parametric binomial test would find this highly significant.
- **4)** Besides lowering muscular tension, EMG biofeedback teaches attention, which may further reduce the difference in outcomes.

#### Duric et al., 2012

130 ADHD children and adolescents, ages 6 to 18, were randomly assigned to receive either 1) NFB, 2) methylphenidate, or 2) combined NFB/medication. After randomization, 39 dropped out (36 immediately after randomization) 13 from the NFB group, 15 from the medication group, 11 from the combined group resulting in 91 completing the study; NFB (n = 30), methylphenidate (n = 31), and combined (n = 30). The NFB group received 30 40-minute theta/beta sessions 3 times per week for 10 weeks. Outcome measures were the inattention and hyperactivity subscales of the parent-rated CMADBD-P (& total score) with the post ADBD-P administered one week after the final NFB session for those in the NFB and combined groups.

- 1) The parents reported highly significant effects of the treatments in reducing the core symptoms of ADHD, but no significant differences between the treatment groups were observed.
- 2) Although not significant, the NFB group showed more than double the pre–post change in attention compared with the other two treatments (3.1 vs. 1.1 and 1.5 for the means) and NFB's effect size was larger than the other two treatments on both the inattention and hyperactivity subscales and total score measures.
- 3) The authors conclude that "NFB produced a significant improvement in the core symptoms of ADHD, which was equivalent to the effects produced by methylphenidate, based on parental reports. This supports the use of NFB as an alternative therapy for children and adolescents with ADHD."

#### Meisel et al., 2013

23 ADHD children, ages7 to 14, were randomly assigned to receive either 40 theta/beta NFB or methylphenidate. Outcome measures were behavioral rating scales completed by fathers, mothers, and teachers at baseline and post-treatment as well as 2 and 6-month follow-up academic performance.

- 1) In both groups, there were similar significant reductions in ADHD functional impairment as rated by parents and in primary ADHD symptoms by parents and teachers.
- 2) Significant academic performance improvements were only detected in the NFB group.
- 3) NFB gains were maintained in both the 2 and 6-month follow-up assessment.

Steiner et al., 2014a.

**104 ADHD children,** ages 7 to 11, were randomly to 40 sessions of NFB (n = 34), computerized cognitive training (CT; n = 34) or waitlist control (n = 36). **Outcome measures** were Conners 3-Parent, Conners 3-Teacher, BRIEF, Behavioral Observation of Students in Schools (BOSS), and dosing of stimulant medications by community physicians.

- 1) NFB children improved significantly more than both the CT and waitlist groups on the Conners 3-Parent, Conners 3-Teacher, and all BRIEF summary indices.
- **2)** NFB children improved significantly more than waitlist on the BOSS.
- **3)** CT children showed no improvement on any measure compared to the waitlist group.
- 4) The clear superiority of NFB over both the CT and waitlist conditions was then sustained in the 6-month follow-up assessment.
  5) NFB was the only group in which there were not significant increases in stimulant medication dosing at both the end of study-directed treatment and the 6-month follow-up assessment.

Note. Behavior Rating Scales: ADDES = Attention Deficit Disorder Evaluation Scale; BRIEF = Behavior Rating Inventory for Executive Function; CBRS = Conners Behavior Rating Scale; CMADBD-P = Clinician's Manual for the Assessment of Disruptive Behavior Disorders – Rating Scale for Parents; CPRS = Conners Parent Rating Scale; CTRS = Conners Teacher Rating Scale; FBB-HKS = German Rating Scale for ADHD FBB-SSV = German Rating Scale for Oppositional Defiant/Conduct Disorders. Tests of Attention: CPT = Continuous Performance Test; IVA = Integrated Visual and Auditory continuous performance task; TOVA = Test of Variables of Attention; TAP = Test for Attentional Performance. Tests of Intelligence: WISC = Wechsler Intelligence Scale for Children

When assessed, NFB resulted in changes in EEG consistent with the NFB protocol that was trained (7 studies) and these changes in EEG self-regulation persisted when reassessed at 6 months (2 studies) and 2 years after treatment termination (1 study). Furthermore in four studies, the researchers correlated the extent of changes in subjects' EEG to ADHD symptom improvement. Similar to Lubar and Shouse (1976, 1979), in each of these studies, those subjects who were most successful in learning to self-regulate their EEG had the greatest improvement in ADHD symptoms *providing additional strong evidence that changing the EEG is the mechanism of change in ADHD symptoms resulting from NFB treatment*. In follow-up studies, NFB resulted in significant improvement in core ADHD symptoms that were sustained when reassessed at six months (5 studies) and 2 years (2 studies) after treatment termination, and *unlike stimulant medications, in no studies have there been any reported adverse effects from NFB*.

Finally, in four studies (combined N = 249), NFB training resulted in improvements equivalent to those achieved by stimulant medication. While two of these studies relied on parental preference versus randomization to determine treatment group assignment, this reflects real-world practice and thereby strengthens the relevance of the results (Fuchs et al., 2003; Rossiter, 2004). The two most recent randomized trials (combined N = 153) found NFB equivalent to stimulant medication in treating ADHD's core symptoms (Duric et al., 2012), with Meisel et al. (2013) reporting sustained improvement for NFB in their 6-month follow-up assessment, and unlike stimulants, only the NFB group achieved significant improvements in academic performance.

#### Conclusion

It is time for professional societies, guideline committees, and healthcare payers to recognize NFB as the best available first-line treatment for ADHD. Given the current first-line treatments' poor real-world outcomes, with no evidence of sustained benefit even with

continued stimulant medication, often prescribed at increasing doses and/or combined with powerful new medications such as antipsychotics and antidepressants (Olfson et al., 2012, 2014; Riddle et al., 2013), ADHD children warrant wide-spread access to methodologically-sound NFB as it is the only treatment with credible evidence documenting sustained improvement in ADHD's core symptoms.

NFB is built on the scientifically-established twin pillars of operant conditioning to teach trainees how to self-regulate targeted aspects of brain functioning and neuroplasticity, which is the brain's ability to rapidly change and reorganize its neural pathways in response to new learning. To promote the advancement of empirically-based NFB, ADHD researchers and clinicians must: 1) demonstrate competence in operant conditioning (Sherlin et al., 2011) and consistently document the extent each NFB trainee learns to self-regulate the targeted brain activity (e.g., plot trainees' session-by-session learning curves), 2) learn to assess how other brain regions of interest are affected, and 3) most importantly, consistently document NFB's impact using relevant psychometric measures to assess the extent of change in each trainee's ADHD core symptoms and psychological functioning (Cannon et al., 2014; Cannon, in press). Such practices need to become the standard of care that all scientist/practitioner NFB clinicians adhere to.

Finally, operant conditioning is a formidable mechanism that has been employed using advanced neuroimaging methods including low-resolution electromagnetic brain tomography (LORETA) and functional magnetic resonance imaging (fMRI). It is noteworthy that researchers using these more advanced NFB technologies still adhere to the fundamental principles of operant conditioning and have shown corresponding positive psychometric outcomes when treating ADHD (Cannon, in press). Such close adherence to operant conditioning must be the case whether employing the established protocols of SMR, theta/beta, or SCP to treat ADHD or one of these neuroimaging-based NFB methods.

In sum, if we are to understand the basic mechanisms of neuronal self-regulation, learning, and their effects on ADHD's core symptoms, all NFB scientist/practitioners must adhere to the guidelines for NFB interventions as outlined at their conception by Professors Sterman, Lubar, and Shouse. Anything less creates more noise than clarity in our pursuit of a cure for ADHD. As the best currently available first-line treatment, ADHD children, their parents, and society-at-large, must learn to accept nothing less from us.

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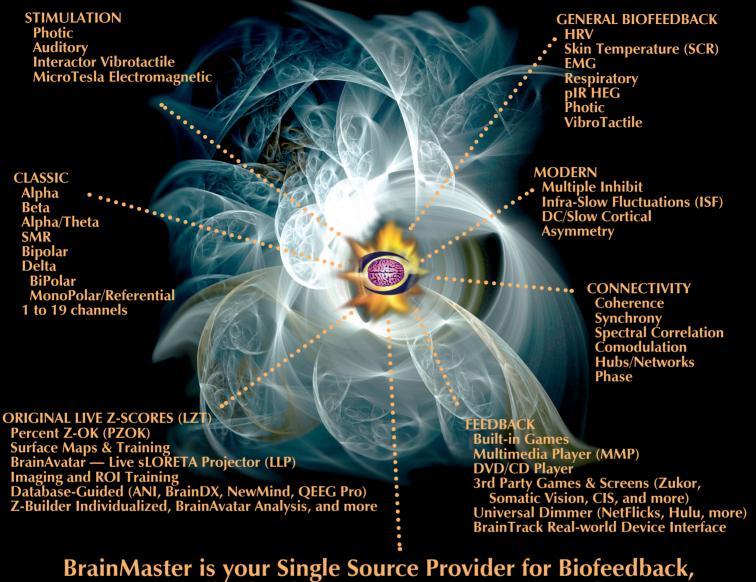
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