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In-School Neurofeedback Training for ADHD: Sustained Improvements From a Randomized Control Trial

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KEY WORDS

ADHD, neurofeedback, biofeedback, cognitive training, growth model

ABBREVIATIONS

ADHD—attention-deficit/hyperactivity disorder
BOSS—Behavioral Observation of Students in Schools
BRIEF—Behavior Rating Inventory of Executive Function
CompAT—computer attention training
Conners 3-P—Conners 3-Parent Assessment Report
CT—cognitive training
RA—research assistant

Dr Steiner conceptualized and designed the study, drafted the initial manuscript, and approved the final manuscript as submitted. Ms Frenette and Ms Rene carried out the initial analyses, reviewed and revised the manuscript, and approved the final manuscript as submitted. Dr Brennan carried out the growth model analyses, reviewed and revised the manuscript, and approved the final manuscript as submitted.

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WHAT'S KNOWN ON THIS SUBJECT: An estimated 9.5% of children are diagnosed with attention-deficit/hyperactivity disorder (ADHD), which affects academic and social outcomes. We previously found significant improvements in ADHD symptoms immediately after neurofeedback training at school.



WHAT THIS STUDY ADDS: This randomized controlled trial included a large sample of elementary school students with ADHD who received in-school computer attention training with neurofeedback or cognitive training. Students who received neurofeedback were reported to have fewer ADHD symptoms 6 months after the intervention.

abstract



OBJECTIVE: To evaluate sustained improvements 6 months after a 40-session, in-school computer attention training intervention using neurofeedback or cognitive training (CT) administered to 7- to 11-year-olds with attention-deficit/hyperactivity disorder (ADHD).

METHODS: One hundred four children were randomly assigned to receive neurofeedback, CT, or a control condition and were evaluated 6 months postintervention. A 3-point growth model assessed change over time across the conditions on the Conners 3-Parent Assessment Report (Conners 3-P), the Behavior Rating Inventory of Executive Function Parent Form (BRIEF), and a systematic double-blinded classroom observation (Behavioral Observation of Students in Schools). Analysis of variance assessed community-initiated changes in stimulant medication.

RESULTS: Parent response rates were 90% at the 6-month follow-up. Six months postintervention, neurofeedback participants maintained significant gains on Conners 3-P (Inattention effect size [ES] = 0.34, Executive Functioning ES = 0.25, Hyperactivity/Impulsivity ES = 0.23) and BRIEF subscales including the Global Executive Composite (ES = 0.31), which remained significantly greater than gains found among children in CT and control conditions. Children in the CT condition showed delayed improvement over immediate postintervention ratings only on Conners 3-P Executive Functioning (ES = 0.18) and 2 BRIEF subscales. At the 6-month follow-up, neurofeedback participants maintained the same stimulant medication dosage, whereas participants in both CT and control conditions showed statistically and clinically significant increases (9 mg [$P = .002$] and 13 mg [$P < .001$], respectively).

CONCLUSIONS: Neurofeedback participants made more prompt and greater improvements in ADHD symptoms, which were sustained at the 6-month follow-up, than did CT participants or those in the control group. This finding suggests that neurofeedback is a promising attention training treatment for children with ADHD. *Pediatrics* 2014;133:483-492

Attention-deficit/hyperactivity disorder (ADHD) is a neurodevelopmental disorder with core symptoms of inattention, hyperactivity, and/or impulsivity and has a prevalence of 9.5% for 4- to 17-year-olds in the United States.¹ Executive functioning is typically impaired in children with ADHD, affecting their academic achievement.² Medication and behavior therapy are both viable treatment options for ADHD,³ but they both have limitations. These limitations, along with the pervasiveness of ADHD symptoms in school, highlight the importance of researching alternative treatments that can be implemented in the classroom setting. Computer attention training (CompAT) is an umbrella term used to describe many computer interventions that appear to be effective⁴ and that might be possible to implement on a large scale in school. Based on theories of operant conditioning and brain plasticity, the goal of CompAT interventions is to decrease ADHD symptoms and improve executive functioning skills. CompAT interventions may provide sustainable benefits even after the intervention is terminated through its conditioning and generalization components. Two types of CompAT interventions were evaluated in the current study: neurofeedback and cognitive training (CT).

EEG patterns in children with ADHD have shown more theta wave activity and increased theta:beta ratio in the frontal cortex, compared with children without ADHD.⁵⁻⁷ Beta Waves in the frontal cortex are associated with sustaining attention and thinking, whereas theta waves are prevalent when drowsy or daydreaming. However, other studies have not confirmed the finding that children with ADHD have elevated theta:beta ratios when compared with controls.^{8,9} The authors of these studies hypothesized that children in control conditions also have elevated theta:beta ratios than has been observed in

the past, potentially due to decreased sleep (among other factors), making the 2 groups look more alike. When training attention, neurofeedback provides children with immediate auditory and visual feedback regarding their level of attention during each exercise. Changes are enabled because of brain plasticity of the frontal brain, which continues to develop throughout childhood and into early adulthood.¹⁰ Neurofeedback therefore trains users to monitor and change their brainwave patterns, leading to behavioral changes.¹¹ Some studies have found that neurofeedback can decrease symptoms of ADHD,¹²⁻¹⁷ including improved attention,¹⁸ behavior,¹⁹ and cognitive improvements²⁰ up to 6 months postintervention as well as at 2 years postintervention.²¹ However, the evidence for its sustainability remains unclear, because there are limited studies examining follow-up data, and those that do have small sample sizes or no control condition.¹³⁻¹⁵ In contrast, CT uses specifically designed exercises to train attention, working memory, and impulsivity through ongoing feedback to reinforce correct responses. Several studies suggest that CT improves performance on working memory tasks and decreases inattentiveness, hyperactivity, and disruptive behaviors.²²⁻²⁶ The largest such trial included only 44 children diagnosed with ADHD, ages 7 to 12 years, and reported results 3 months after completing a 20-session intervention.²⁶ Gevensleben et al¹⁸ examined neurofeedback and CT after 6 months and found that improvements in the neurofeedback condition on parent-reported behavior scales were significantly superior and sustained compared with the CT condition. Unfortunately, significant attrition makes this study's generalizability unclear. A recent meta-analysis regarding nonpharmacologic interventions for ADHD concluded that increased evidence is needed for both

neurofeedback and CT interventions before they can be supported as treatments for ADHD.²⁷

The current study is novel for several reasons. The research team conducted the first in-school translational efficacy trial comparing neurofeedback, CT, and control conditions. Previous studies have mostly been conducted in laboratories or in clinical settings. This efficacy trial targeted a precise age range of children 7 to 11 years of age, as opposed to previous studies that included diverse developmental age ranges. Many studies are smaller without a control group and failed to find group differences. Last, very few studies reported follow-up results.

Pre- to postintervention, we found significantly greater improvements in ADHD symptoms, including attention and executive functioning, among neurofeedback participants compared with the control and CT conditions.²⁸ In the present article, we report outcomes 6 months after the conclusion of the intervention. We hypothesized that participants receiving neurofeedback would maintain improvements in attention and executive functioning compared with control or CT conditions and that medication dosage would remain stable.

METHODS

Participants

Students with ADHD who were attending 1 of 19 public elementary suburban or urban schools in the Greater Boston area were eligible to participate in the randomized trial. Inclusion criteria included the following: (1) child in second or fourth grade, (2) clinical diagnosis of ADHD made by the child's clinician, and (3) ability to speak and understand English well enough to follow the protocol, although English was not necessarily the participant's first language. Exclusion criteria included (1) a coexisting diagnosis of conduct disorder, autism spectrum disorder, or other

serious mental illness (eg, psychosis) and (2) an IQ measured by the Kaufman Brief Intelligence Test <80, to limit confounding factors and requirements of extensive amendments to the intervention protocol that could affect standardized implementation. The study was located in schools, and investigators had no clinical responsibility for the children's medical care. Therefore, children were included on the basis of their clinician's diagnosis of ADHD, and were included regardless of whether they were taking medications for ADHD. Parents of all participants were informed that they should continue to adhere to scheduled clinician visits and standard community treatments (including counseling and medication management) independent of study participation, and medication use was not suspended for treatments or assessments. The study was approved by the Tufts Medical Center Institutional Review Board, and written informed consent and child assent were obtained. Enrollment of the first cohort occurred from May to September 2009 and from May to September 2010 for the second cohort. All preintervention assessments were conducted in October, and interventions were initiated in November of each year. For each cohort, the research coordinator balanced participants on the basis of school district, gender, and medication status, and then assigned them via a computer random number generator into 3 conditions (neurofeedback, CT, and control). Before enrollment, parents were told their child would be randomly assigned into 1 of these 3 conditions, and were informed of their child's group status after assignments were made.

Interventions

Participants received in-school 45-minute intervention sessions 3 times per week, monitored by a trained research assistant (RA), for 40 sessions over 5 months. The same protocol was used for both intervention conditions.

RAs received a standardized 2-week training to administer neurofeedback and CT, followed by a posttraining test and direct observation assessments. RAs filled out a standardized session checklist for each child at every session to monitor implementation fidelity.

The specific neurofeedback system used (Play Attention, Unique Logic and Technology, Fletcher, NC) detects 2 frequency ranges, 1 in the low-frequency theta brainwave range (4–8 Hz) and another in the high-frequency beta brainwave range (12–15 Hz).²⁹ The brainwaves are measured by an EEG sensor embedded in a standard bicycle helmet centrally located on the top of the skull, and 2 other EEG sensors one a grounding sensor and the other a reference, on the chin straps located bilaterally on the mastoids. Through practice, participants learn to manipulate the figures on the screen, resulting in suppression of theta and an increase in beta activity. As the theta:beta ratio changes, an algorithm is used so that participants score points on the computer program and learn how to improve attention on the 6 different exercises.

The specific CT intervention used (Captain's Log, BrainTrain, North Chesterfield, VA) comprises exercises that train different areas of cognition, which may be designed into personalized exercise protocols. The system is well designed for large-scale delivery, because there is automatic level advancement after each exercise.³⁰ The standardized protocol developed for this study is composed of 14 auditory and visual exercises targeting areas of attention and working memory. Each exercise is interactive and lasts ~5 minutes. Both systems are commercially available.

Primary Outcome Measures

Outcome measures included parent reports of ADHD symptoms and executive functioning, medication use, and systematic classroom observations of

behavior. All outcome measures were obtained pre- and postintervention, and 6 months later.

The Conners 3–Parent Assessment Report (Conners 3-P; Multi-Health Systems Inc, North Tonawanda, NY) is a validated and standardized instrument to assess ADHD symptoms,³¹ including 9 subscales comprising 2 summary scales summed together as a Global Index. The Behavior Rating Inventory of Executive Function (BRIEF) (PAR Inc, Lutz, FL) is a validated and standardized instrument that assesses executive functioning,³² including 8 subscales comprising 2 indices summed together in the Global Executive Composite. Both parents, if available, completed the Conners 3-P and BRIEF.

The Behavioral Observation of Students in Schools (BOSS; Pearson Education, Inc, New York, NY)³³ is a systematic interval recording observation system for coding classroom behavior and reports on engagement (active or passive) and off-task behaviors (motor, verbal, and passive). Data output from observations are objective quantitative assessments, which can help reduce observer bias, and consist of raw data as well as the percentage of intervals the participant was recorded as engaged or off-task. The BOSS has been found to be reliable between observers,³⁴ to differentiate between children with ADHD and their typically developing peers,³⁵ and to be sensitive to treatment effects.³⁶ The BOSS was completed 3 times at each time point (ie, before the intervention, immediately after the intervention, and 6 months after the intervention) for all study participants by trained RAs³⁷ who were unaware of the participants' randomization conditions. The participants were unaware that they were being observed.

A Medication Tracking Questionnaire was completed by the primary parent at each time point to track medication type, dosage, and history. No direct

consultation regarding medication was discussed with parents, who were encouraged to continue their regularly scheduled visits with their clinician. Stimulant medications were converted into methylphenidate equivalencies by the research team to compare dosage over time. The reliability of parent reports was assessed by comparing name and dosages of medication at each time point. Ambiguous responses were clarified by direct communication with parents and clinicians.

Data Analysis

Analysis of variance was conducted to assess baseline differences in demographic data between randomization conditions. Missing items within multiitem scales were resolved by using expectation maximization imputation,³⁸ which is an iterative imputation method suitable for low-frequency missing data and/or when SEs are not of primary concern.³⁹ When a full questionnaire was missing, it was dropped from the analysis and addressed directly through the analytic strategy described below. Because this study investigated whether the 2 CompAT interventions are superior to community treatment alone, and whether neurofeedback is superior to CT, this randomized controlled trial is considered a superiority trial and analyses are presented with 1-tailed tests.^{40–42}

The central focus of these analyses was to evaluate whether the observed changes in core ADHD symptoms between the start and end of the treatment period were sustained at the 6-month follow-up. Changes in parent-reported and classroom observation measures were investigated by 3-point growth models by using a multilevel approach to assess change over the 3 time points (preintervention, postintervention, and 6-month follow-up) to compare neurofeedback and CT with the control.^{43–45} Our approach used all available data, including the reports from 2 parents when available at all 3 time points.

These models allow for the estimation of reliability of measurement and change within the overall estimation, and can flexibly accommodate unbalanced data, so a participant can be included at a time point even if only 1 parent questionnaire was available at any or all of the time points. For the BOSS, 3 observations at all 3 time points were used to estimate reliability.⁴⁶ This linear model estimates the best-fitting line to the 3 time points. Comparisons between neurofeedback and CT were undertaken using multivariate general linear hypothesis tests.⁴⁷ For ease in interpretation and comparison with other studies, approximate effects sizes (expressed as standardized mean differences, Cohen's *d*) were computed from the neurofeedback and CT coefficients from the growth models; however, to the best of our knowledge, no other study of CompAT reports growth coefficients and, furthermore, standard calculations do not accommodate all of the parameters estimated in a multilevel model.⁴⁸ All growth models were estimated by using HLM version 7.0.⁴² All other analyses and data treatment were conducted by using SYSTAT version 13.0.⁴⁹

Paired *t* tests were conducted to evaluate stimulant medication differences in methylphenidate equivalencies within randomization conditions between preintervention and the 6-month follow-up. An analysis of covariance was conducted to evaluate medication dosage differences among the randomization conditions at 6-month follow-up, controlling for preintervention stimulant medication dosages.

RESULTS

Of the 104 children in the study, 102 completed the intervention. Of these, only 4 did not complete the 6-month follow-up assessment ($n = 98$) (Fig 1). The mean response rates of the parent questionnaires for pre- and postintervention data were 94% for the primary

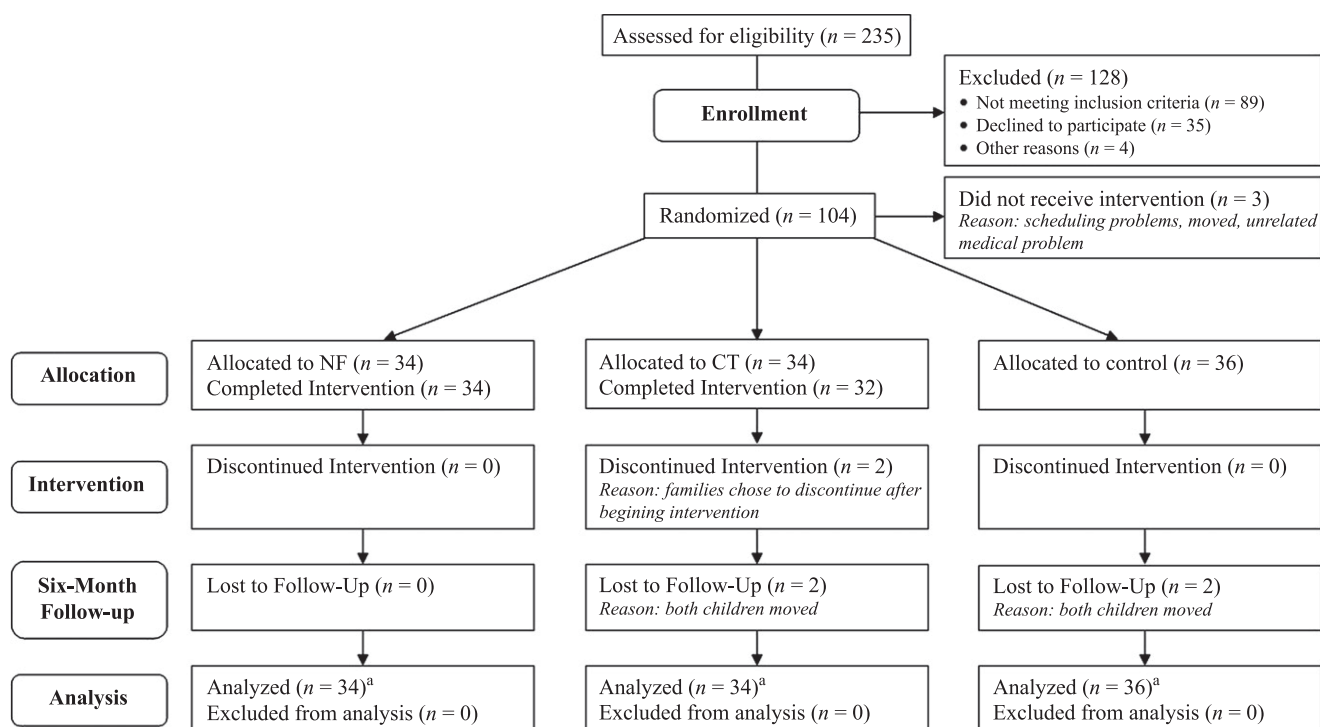
parent and 77% for the secondary parent. At the 6-month follow-up, response rates were 90% for the primary parent and 82% for the secondary parent. The BOSS was completed 3 times for each participant at preintervention, postintervention, and 6-month follow-up for 100% of participants. At baseline, 95% of participants showed clinically significant scores ≥ 65 on the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*, ADHD Inattention and/or ADHD Hyperactive-Impulsive subscales. At baseline, 49% of participants were taking medication. There were no statistically significant differences between randomization conditions at baseline with regard to gender, family income, race, medication use, or baseline ADHD symptoms (Table 1). There were no significant differences between participants who completed or who did not complete the intervention, or between randomization conditions at 6-month follow-up regarding gender, family income, or race. There were no adverse side effects in neurofeedback or CT interventions reported on the session checklists.

Growth Model Analysis

The majority of distributions for the measures at each time point and the changes were approximately symmetrical and tailed, but normality could not be assumed for all scales, so we relied on the robust SEs available in HLM⁴² in the assessment of hypotheses in the Conners 3-P, BRIEF, and BOSS models. The slopes of the primary scales of research interest on the Conners 3-P, BRIEF, and BOSS are displayed to show change over time by condition.

Parent-Reported Measures

Participants in the neurofeedback condition showed significant improvements over time compared with the control condition on Conners 3-P in the intervention-targeted areas of inattention, executive functioning, and hyperactivity/impulsivity

**FIGURE 1**

CONSORT (Consolidated Standards of Reporting Trials) diagram. ^a In a small number of cases, parent or teacher data were missing; therefore, sample sizes may be somewhat smaller than is indicated here.

as well as in 4 of 6 general behavior subscales (Table 2 and Supplemental Table 4) and on all 3 BRIEF summary index scales as well as 7 of 8 BRIEF subscales

(Table 2 and Supplemental Table 5). Participants in the CT condition showed significant improvements over time compared with the control on only 1 of

the 5 Conners 3-P subscales (Table 2) and on 2 of 8 BRIEF subscales (Supplemental Table 5). Furthermore, participants in the neurofeedback condition showed significant improvements over time compared with the CT condition on 6 Conners 3-P subscales (Supplemental Table 4) and on 6 BRIEF subscales (Supplemental Table 5). See Fig 2 for observed participant mean scores across the 3 study time points by condition in core ADHD and executive functioning areas.

TABLE 1 Participant Characteristics

	NF	CT	Control
<i>n</i>	34	34	36
Age, mean (SD), <i>y</i>	8.4 (1.1)	8.9 (1.0)	8.4 (1.1)
Male gender, <i>n</i>	23	22	25
Race, <i>n</i>			
White	23	24	29
Black or African American	3	1	3
Asian	7	8	4
Fourth grade ^a , <i>n</i>	21	28	22
Family income ≤\$74 999, <i>n</i>	13	12	12
Suburban school district, <i>n</i>	24	25	27
IQ, mean (SD)			
IQ composite	106.6 (13.9)	108.4 (14.3)	108.9 (15.4)
Verbal IQ	101.3 (16.7)	103.9 (19.4)	105.1 (16.3)
Nonverbal IQ	109.6 (12.5)	110.2 (12.1)	109.7 (17.7)
ADHD medication, <i>n</i>	15	14	20
Medication MPH equivalent ^b , mean (SD)	28.9 (14.4)	24.2 (10.2)	25.1 (15.9)
Counseling (private), <i>n</i>	9	7	8
School services: IEP/504 Plan, <i>n</i>	27	22	21
Conners 3-P Global Index, mean (SD)	75.77 (13.46)	70.89 (10.85)	74.61 (12.08)
BRIEF Global Executive Composite, mean (SD)	66.30 (10.00)	61.75 (6.59)	64.65 (9.02)
BOSS Engaged, mean (SD)	72.16 (12.40)	73.37 (13.30)	78.20 (11.67)
BOSS Off-Task, mean (SD)	30.17 (17.10)	25.87 (15.05)	21.14 (13.87)

IEP, Individualized Education Plan; MPH, methylphenidate; NF, neurofeedback.

^a Significant difference between conditions.

^b Only includes participants who were taking a stimulant medication.

Classroom Observation

Results from the linear growth model did not show sustained change; however, the linear model was not a good fit for Off-task Motor/Verbal, therefore a quadratic model was estimated and significant improvements were found in the neurofeedback condition compared with the control ($P = .04$). There were no differences found between neurofeedback and CT conditions on classroom observation measures (Table 3).

TABLE 2 Primary Measures: Parent Results

	Observed Data ^a			Growth Model Estimates ^b					
	Preintervention	Postintervention	Six-Month Follow-up	Coefficient	95% CI	NF Versus Control	CT Versus Control	NF Versus CT	Approximate Effect Size ^c
Conners 3-P—core ADHD symptoms									
Inattention									
Control	76.72 (10.02)	75.16 (10.47)	74.58 (10.03)	-1.26	-2.56 to 0.05				-0.12
NF	80.07 (10.77)	71.43 (10.79)	70.06 (13.17)	-3.67	-5.81 to -1.52	**			-0.34
CT	74.78 (9.50)	70.21 (10.31)	67.56 (9.05)	-1.55	-3.75 to 0.64				-0.14
DSM-IV-ADHD Inattention									
Control	75.45 (11.20)	73.90 (11.91)	73.42 (11.45)	-1.25	-2.31 to -0.19				-0.11
NF	79.20 (11.65)	70.13 (11.76)	68.45 (14.30)	-3.45	-5.36 to -1.55	**			-0.29
CT	73.48 (10.11)	70.07 (10.51)	66.13 (11.91)	-1.88	-3.78 to 0.02				-0.16
Executive Functioning									
Control	69.26 (11.64)	70.36 (12.56)	70.52 (12.38)	-0.10	-1.14 to 0.94				-0.0082
NF	72.23 (12.16)	65.97 (13.16)	65.00(14.65)	-3.02	-4.88 to -1.16	**			-0.25
CT	67.46 (12.04)	66.00 (12.12)	62.45 (11.28)	-2.18	-3.91 to -0.45		*		-0.18
Hyperactivity/Impulsivity									
Control	77.03 (13.77)	75.42 (14.51)	77.16 (13.60)	0.67	-0.53 to 1.87				0.05
NF	76.92 (13.54)	72.73 (14.38)	72.36 (16.34)	-3.19	-5.27 to -1.11	**			-0.23
CT	72.04 (13.69)	73.07 (15.75)	72.19 (12.92)	-0.03	-1.91 to 1.85				-0.01
DSM-IV-ADHD Hyperactive-Impulsive									
Control	75.45 (13.61)	74.84 (14.00)	65.16 (14.41)	1.11	-0.12 to 2.35			**	0.08
NF	75.43 (13.76)	71.33 (14.51)	72.14 (15.94)	-2.90	-4.91 to -0.90	**			-0.21
CT	69.00 (13.71)	71.43 (15.73)	71.01 (13.25)	0.34	-1.47 to 2.15				-0.02
BRIEF—summary indices									
Behavior Regulation Index									
Control	60.84 (11.62)	61.36 (10.35)	60.39 (11.79)	0.39	-0.64 to 1.42				0.04
NF	62.43 (11.52)	59.03 (10.05)	59.82 (11.70)	-2.43	-4.22 to -0.65	*			-0.23
CT	59.29 (8.65)	59.86 (10.28)	59.07 (9.60)	-0.50	-1.97 to 0.97				-0.05
Metacognition Index									
Control	65.45 (8.41)	65.48 (9.45)	67.13 (8.07)	0.26	-0.56 to 1.08				0.03
NF	66.93 (9.69)	62.77 (9.09)	60.80 (12.37)	-2.92	-4.50 to -1.35	**			-0.33
CT	62.14 (6.67)	61.33 (8.22)	60.21 (7.87)	-0.91	-2.20 to 0.39				-0.10
Global Executive Composite									
Control	64.65 (9.02)	64.81 (9.04)	65.48 (8.36)	0.23	-0.65 to 1.10				0.0249
NF	66.30 (10.00)	62.07 (8.86)	61.02 (11.57)	-2.75	-4.37 to -1.13	**		*	-0.31
CT	61.75 (6.59)	61.46 (8.30)	60.29 (7.30)	-0.65	-1.96 to 0.65				-0.07

CI, confidence interval; DSM-IV, *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition*; NF, neurofeedback.

^a Data are presented as means (SD).

^b The growth model coefficient estimates for NF and CT represent the difference in the linear slopes between the intervention conditions and the control condition over the 3 time points. A multivariate general linear hypothesis test was conducted to determine differences between the NF and CT slopes over the 3 time points.

^c Approximate effect size estimate for linear growth coefficient.

* $P < .05$, ** $P < .01$.

Medication Analysis

Among participants receiving stimulant medication, the mean dosage change in the neurofeedback condition from pre-intervention to 6-month follow-up was a 0.70-mg methylphenidate-equivalent increase ($P = .44$). In both CT and control conditions, parents reported significant increases: 13.08 mg for CT ($P = .02$) and 9.14 mg for the control ($P < .001$). No between-group dosage difference was found at 6-month follow-up, controlling for preintervention ($P = .08$).

DISCUSSION

The outcomes of these analyses are promising. Parents of children in the neurofeedback condition reported sustained improvements 6 months after the intervention, compared with those in the control condition. In the CT condition,

areas of executive functioning that did not show statistically significant change immediately after the intervention showed a significant change by the 6-month follow-up assessment compared with the control condition. Even after the intervention had stopped, parents continued to notice improvements in response to both interventions. Although similar to the Arns et al¹² meta-analysis, improvements seen in the hyperactivity/impulsivity-related scales in the neurofeedback condition are surprising, because hyperactivity was not directly targeted in the intervention. Nevertheless, these findings suggest that when children's focus increases, physical activity level is reduced.

Clinician's management of medication was conducted independently of the study protocol. It is noteworthy that participants in the neurofeedback condition

showed maintenance of stimulant medication dosage while presumably experiencing the same physical growth and increased school demands as CT and control condition peers, whose medication dosage increased clinically and statistically (9- to 13-mg methylphenidate-equivalent units).

This study used multiple sources and types of data including questionnaires from parents, systematic classroom observations of behavior, and medication. Because children had a different teacher at pre- and postintervention compared with the 6-month follow-up, teacher reports were not included in these analyses. The inclusion of the systematic classroom observations provided a valid double-blinded representation of the children's behavior in the classroom.

Randomization of subjects to treatment conditions, as applied in this study, is the gold standard for clinical trials. Even though stratified by gender, school system, and medication status and well balanced regarding demographic characteristics across all 3 randomized conditions, the participants in the 3 conditions appeared to differ in the severity of baseline ADHD symptoms. However, none of these differences reached significance, and it is unclear how these differences in baseline severity might have affected the results. Furthermore, we relied on growth models to isolate change over time, not status at post-treatment or follow-up; our time coding, which centered time at posttreatment, was selected to reduce the correlation of initial status and change.

Parents were aware of the type of intervention their child received, which was unavoidable, because 1 of the systems uses a helmet and the other does not. Parents were informed that the 2 interventions were both commercially available and had achieved similarly encouraging results in previous studies at the time of enrollment. At postintervention, we found no differences in

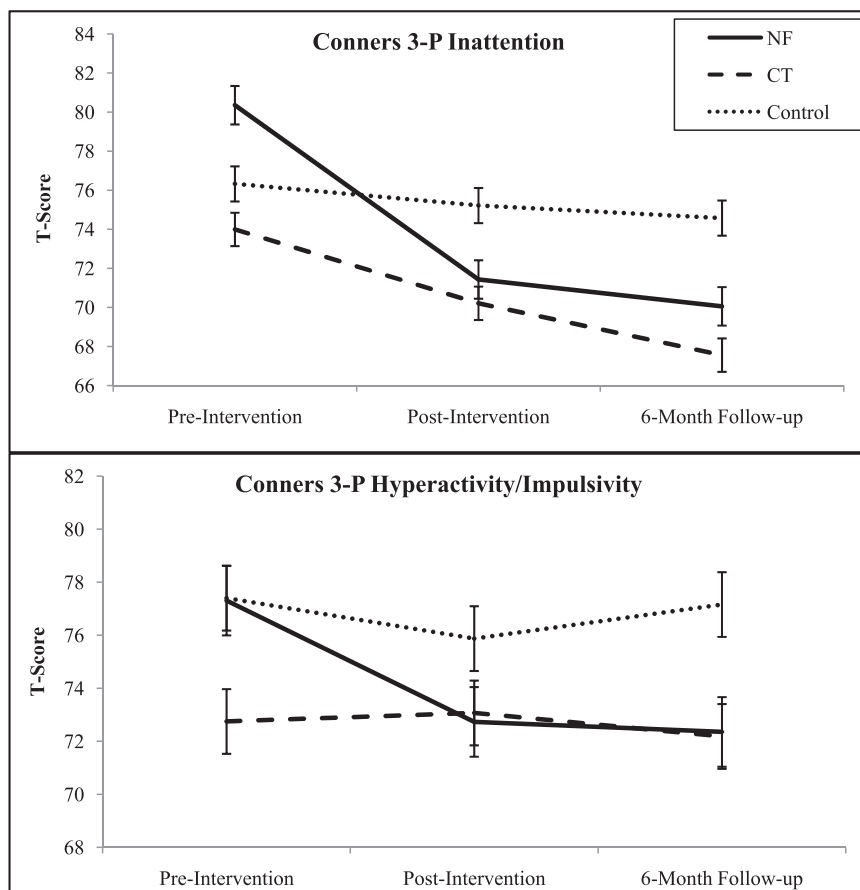


FIGURE 2 Observed participant mean scores across 3 study time points. NF, neurofeedback.

TABLE 3 BOSS Results

	Observed Data ^a			Growth Model Estimates ^b		
	Preintervention	Postintervention	Six-Month Follow-Up	Coefficient	95% CI	Effect Size ^d
Engaged						
Control	78.20 (11.67)	79.34 (13.58)	81.23 (10.37)	1.49	−0.87 to 3.86	0.04
NF	72.16 (12.40)	77.98 (14.60)	77.76 (13.43)	1.57	−1.70 to 4.85	0.04
CT	73.37 (13.30)	77.10 (13.58)	76.16 (15.97)	0.06	−3.84 to 3.97	0.002
Off-Task Motor/Verbal ^c						
Control	21.14 (13.87)	18.44 (11.95)	19.11 (11.13)	−1.04	−3.39 to 1.31	0.03
NF	30.17 (17.10)	20.81 (14.21)	22.69 (16.60)	−1.86	−6.02 to 2.29	−0.05
CT	25.87 (15.05)	20.03 (10.88)	23.96 (5.93)	−0.49	−4.41 to 3.43	−0.01

CI, confidence interval; NF, neurofeedback.

^a Data are presented as means (SD).

^b The growth model estimates a coefficient representing a change in the slope between the intervention conditions and the control condition over the 3 time points.

^c Quadratic model also estimated (see text); results of the linear model shown.

^d Approximate effect size estimate for linear growth coefficient.

satisfaction with the intervention between parents with participants in the neurofeedback condition and parents with participants in the CT condition, suggesting that parent bias most likely did not affect their reporting of the measures.

CONCLUSIONS

Neurofeedback participants showed significant improvements that were sustained 6 months after the intervention compared with those in the control and CT conditions, as reported by the parents consistently on all of the core ADHD subscales and executive functioning scales. Participants in the CT condition showed significant improvement 6 months after the intervention period on 2 executive functioning subscales. Medication dosage was sustained among participants in the neurofeedback condition, whereas for CT and control conditions it was increased. The finding that neurofeedback was superior to CT on multiple scales further supports its efficacy as a treatment of children with ADHD. Effects were

reported earlier in the neurofeedback condition than in the CT condition and were also stronger at the 6-month follow-up period, showing the promise of neurofeedback as a treatment with sustained gains for children with ADHD. This is the first large randomized controlled trial to evaluate the long-term efficacy of in-school CompAT. Despite the paucity of scientific data, both neurofeedback and CT training systems are currently being used in school systems across the United States,^{29,30} underlining the importance of systematic studies of their effectiveness. The direct impact of attention deficits on academic progress makes schools an ideal setting for such an intervention, because all children with ADHD in all communities could potentially have access to these services on an ongoing basis. A next important step will be to assess individual participant differences to evaluate which factors might be associated with the most progress on the respective interventions and to study older developmental age cohorts.

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REFERENCES

1. Visser SN, Bitsko RH, Danielson ML, Perou R & Blumberg SJ, et al. Increasing prevalence of parent-reported attention-deficit/hyperactivity disorder among children—United States 2003 and 2007. *Morbidity and Mortality Weekly Report*. 2010;59(44):1439–1443
2. Biederman J, Monuteaux MC, Doyle AE, et al. Impact of executive function deficits and attention-deficit/hyperactivity disorder (ADHD) on academic outcomes in children. *J Consult Clin Psychol*. 2004;72(5):757–766
3. The MTA Cooperative Group. Multimodal Treatment Study of Children with ADHD: a 14-month randomized clinical trial of treatment strategies for attention-deficit/hyperactivity disorder. *Arch Gen Psychiatry*. 1999;56(12):1073–1086

4. Steiner NJ, Sheldrick RC, Gotthelf D, Perrin EC. Computer-based attention training in the schools for children with attention deficit/hyperactivity disorder: a preliminary trial. *Clin Pediatr (Phila)*. 2011;50(7):615–622
5. Loo SK, Barkley RA. Clinical utility of EEG in attention deficit hyperactivity disorder. *Appl Neuropsychol*. 2005;12(2):64–76
6. Loo SK, Makeig S. Clinical utility of EEG in attention-deficit/hyperactivity disorder: a research update. *Neurotherapeutics*. 2012;9(3):569–587
7. Monastra VJ, Lynn S, Linden M, Lubar JF, Gruzelier J, LaVaque TJ. Electroencephalographic biofeedback in the treatment of attention-deficit/hyperactivity disorder. *Appl Psychophysiol Biofeedback*. 2005;30(2):95–114
8. Liechti MD, Valko L, Müller UC, et al. Diagnostic value of resting electroencephalogram in attention-deficit/hyperactivity disorder across the lifespan. *Brain Topogr*. 2013;26(1):135–151
9. Arns M, Conners CK, Kraemer HC. A decade of EEG theta/beta ratio research in ADHD: a meta-analysis. *J Atten Disord*. 2013;17(5):374–383
10. Giedd JN, Rapoport JL. Structural MRI of pediatric brain development: what have we learned and where are we going? *Neuron*. 2010;67(5):728–734
11. Heinrich H, Gevensleben H, Strehl U. Annotation: neurofeedback—train your brain to train behavior. *J Child Psychol Psychiatry*. 2007;48(1):3–16
12. Arns M, de Ridder S, Strehl U, Breteler M, Coenen A. Efficacy of neurofeedback treatment in ADHD: the effects on inattention, impulsivity and hyperactivity: a meta-analysis. *Clin EEG Neurosci*. 2009;40(3):180–189
13. Moriyama TS, Polanczyk G, Caye A, Banaschewski T, Brandeis D, Rohde LA. Evidence-based information on the clinical use of neurofeedback for ADHD. *Neurotherapeutics*. 2012;9(3):588–598
14. Arns M, Drinkenburg W, Leon Kenemans J. The effects of QEEG-informed neurofeedback in ADHD: an open-label pilot study. *Appl Psychophysiol Biofeedback*. 2012;37(3):171–180
15. Hodgson K, Hutchinson AD, Denson L. Non-pharmacological treatments for ADHD: a meta-analytic review. *J Atten Disord*. 2012; doi: 10.1177/1087054712444732.
16. Gevensleben H, Holl B, Albrecht B, et al. Is neurofeedback an efficacious treatment for ADHD? A randomised controlled clinical trial. *J Child Psychol Psychiatry*. 2009;50(7):780–789
17. Williams JM. Does neurofeedback help reduce attention-deficit hyperactivity disorder? *J Neurother*. 2010;14(4):261–279
18. Gevensleben H, Holl B, Albrecht B, et al. Neurofeedback training in children with ADHD: 6-month follow-up of a randomised controlled trial. *Eur Child Adolesc Psychiatry*. 2010;19(9):715–724
19. Strehl U, Leins U, Goth G, Klingner C, Hinterberger T, Birbaumer N. Self-regulation of slow cortical potentials: a new treatment for children with attention-deficit/hyperactivity disorder. *Pediatrics*. 2006;118(5). Available at: www.pediatrics.org/cgi/content/full/118/5/e1530
20. Leins U, Goth G, Hinterberger T, Klingner C, Rumpf N, Strehl U. Neurofeedback for children with ADHD: a comparison of SCP and theta/beta protocols. *Appl Psychophysiol Biofeedback*. 2007;32(2):73–88
21. Gani C, Birbaumer N, Strehl U. Long term effects after feedback of slow cortical potentials and of theta-beta amplitudes in children with attention-deficit/hyperactivity disorder (ADHD). *Int J Bioelectromagn*. 2008;10(4):209–232
22. Rabiner DL, Murray DW, Skinner AT, Malone PS. A randomized trial of two promising computer-based interventions for students with attention difficulties. *J Abnorm Child Psychol*. 2010;38(1):131–142
23. Holmes J, Gathercole SE, Place M, Dunning DL, Hilton KA, Elliott JG. Working memory deficits can be overcome: impacts of training and medication on working memory in children with ADHD. *Appl Cogn Psychol*. 2010;24(6):827–836
24. Loo SK, Barkley RA. Clinical utility of EEG in attention deficit hyperactivity disorder. *Appl Neuropsychol*. 2005;12(2):64–76
25. Monastra VJ, Lynn S, Linden M, Lubar JF, Gruzelier J, LaVaque TJ. Electroencephalographic biofeedback in the treatment of attention-deficit/hyperactivity disorder. *J Neurother*. 2005;9(4):5–34
26. Klingberg T, Fernell E, Olesen PJ, et al. Computerized training of working memory in children with ADHD—a randomized, controlled trial. *J Am Acad Child Adolesc Psychiatry*. 2005;44(2):177–186
27. Sonuga-Barke EJS, Brandeis D, Cortese S, et al; European ADHD Guidelines Group. Nonpharmacological interventions for ADHD: systematic review and meta-analyses of randomized controlled trials of dietary and psychological treatments. *Am J Psychiatry*. 2013;170(3):275–289
28. Steiner NS, Frenette EC, Rene KR, Brennan RT, Perrin EC. Neurofeedback and cognitive attention training for children with attention deficit/hyperactivity disorder in schools. *J Dev Behav Pediatr*. 2013;35:18–27
29. Play Attention [home page on the Internet]. Available at: www.playattention.com. Accessed August 22, 2013
30. BrainTrain [home page on the Internet]. Available at: www.braintrain.com. Accessed August 21, 2013
31. Conners CK, Wells KC, Parker JD, Sitarenios G, Diamond JM, Powell JW. A new self-report scale for assessment of adolescent psychopathology: factor structure, reliability, validity, and diagnostic sensitivity. *J Abnorm Child Psychol*. 1997;25(6):487–497
32. Mahone EM, Cirino PT, Cutting LE, et al. Validity of the behavior rating inventory of executive function in children with ADHD and/or Tourette syndrome. *Arch Clin Neuropsychol*. 2002;17(7):643–662
33. Shapiro ES. *Academic Skills Problems*. 4th Ed. Workbook. New York, NY: The Guilford Press; 2011
34. Swanson JM. *School-Based Assessments and Interventions for ADD Students*. Irvine, CA: KC Publishing; 1992
35. DuPaul GJ, Volpe RJ, Jitendra AK, Lutz JG, Lorah KS, Gruber R. Elementary school students with AD/HD: predictors for academic achievement. *J Sch Psychol*. 2004;42:285–301
36. Volpe R, DiPerna J, Hintze J, Shapiro E. Observing students in classroom settings: a review of seven coding schemes. *School Psych Rev*. 2005;34(4):454–474
37. Steiner NJ, Sidhu TK, Rene KM, Tomasetti KM, Frenette EC, Brennan RT. Development and testing of a direct observation code training protocol for elementary aged students with attention deficit/hyperactivity disorder. *Educ Asse Eval Acc*. DOI 10.1007/s11092-013-9166-x
38. Dempster AP, Laird NM, Rubin DB. Maximum likelihood from incomplete data via the EM algorithm. *J R Stat Soc Series B Stat Methodol*. 1977;39(1):1–38
39. Enders C. A primer on maximum likelihood algorithms available for use with missing data. *Struct Equ Modeling*. 2001;8(1):128–141
40. Sackett DL. Superiority trials, non-inferiority trials, and prisoners of the 2-sided null hypothesis. *Evid Based Med*. 2004;9(2):38–39
41. Piaggio G, Elbourne DR, Altman DG, Pocock SJ, Evans SJ; CONSORT Group. Reporting of noninferiority and equivalence randomized trials: an extension of the CONSORT statement. *JAMA*. 2006;295(10):1152–1160
42. Raudenbush S, Bryk A, Congdon R. *HLM 7: Hierarchical Linear & Nonlinear Modeling*.

Skokie, IL: Scientific Software International; 2011

43. Goldberg AE, Sayer A. Lesbian couples' relationship quality across the transition to parenthood. *J Marriage Fam.* 2006;68(1): 87–100
44. Goldberg AE, Smith JZ. The social context of lesbian mothers' anxiety during early parenthood. *Parent Sci Pract.* 2008;8(3):213–239
45. Goldberg AE, Smith JZ. Stigma, social context, and mental health: lesbian and gay couples across the transition to adoptive parenthood. *J Couns Psychol.* 2011;58(1): 139–150
46. Raudenbush SW, Brennan RT, Barnett RC. A multivariate hierarchical model for studying psychological change within married couples. *J Fam Psychol.* 1995;9(2):161
47. Raudenbush SW, Bryk AS. *Hierarchical Linear Models: Applications and Data Analysis Methods.* Thousand Oaks, CA: Sage; 2002
48. Wilson DB. Effect size calculator. Available at: www.campbellcollaboration.org/escalc/html/EffectSizeCalculator-Home.php. Accessed August 22, 2013
49. Systat Software, Inc. *SYSTAT 13.0.* Richmond, CA: CA Systat Software, Inc; 2008

ADULT TASTES: *Last week I was at the frozen food section of the supermarket staring at rows of frozen desserts and practically rendered immobile by indecision. I was looking for a special frozen dessert for a friend of mine who likes dessert and specifically chocolate ones. Of course, there were many varieties of chocolate, chocolate chip, and chocolate fudge ice creams. However, I was drawn to the gelatos, possibly because of my culinary experiences while traveling in Italy, but also because of gelato's remarkable flavors. I could choose from Argentine caramel, Belgium milk chocolate, and German Chocolate Cake. I eventually settled on a pint of Sea Salt Caramel gelato despite the fact that it cost more than a half-gallon of ice cream. Evidently, I am not the only adult captivated by the rich flavors found in gelato and willing to pay a bit more for the experience. As reported in The Wall Street Journal (Life & Culture: November 12, 2013), sales of gelato in the US jumped almost 90% in 2012 while sales of ice cream and ice cream products remained flat. Gelato and premium ice cream makers have been attempting to lure adults into buying more for themselves by introducing more complex and exotic flavors. The interest in more obscure flavors may be due to the spread of the food culture through TV shows and social media. Occasionally, the flavors do not work out well. For example, tasters found a peach-champagne sorbetto (a non-dairy gelato) with mint to be too intense and the line was dropped. As for me, I am thrilled with all the new flavors. Still, I tend to gravitate to the caramel gelatos which for at least one company have become the top selling gelatos – selling even more than vanilla. As for my friend, she was very pleased with my selection, as was I.*

Noted by WVR, MD

In-School Neurofeedback Training for ADHD: Sustained Improvements From a Randomized Control Trial

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