



Effect of the Brain Balance Program[®] on Cognitive Performance in Children and Adolescents with Developmental and Attentional Issues

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Authors' contributions

This work was carried out in collaboration between both the authors. Author RJ designed the study, wrote the protocol and contributed to the manuscript. Author CJW managed the analyses of the study and manuscript contribution. Both authors read and approved the final manuscript.

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ABSTRACT

We reviewed the cognitive task performance of children and adolescents with developmental and attentional issues, before and after participation in the Brain Balance[®] (BB) program. The program consisted of three 1-hour sessions/week (sensorimotor stimulation and academic activities) with other multimodal activities, for 3 months. Participants were compared to a control group that had the same underlying demographic and phenotypical features but did not yet complete the program (participated on average for 27 days). For all ages (4-6 and 7+ years), we found a significant main effect of group, such that BB groups improved overall more than controls (CTRLs). More specifically, BB groups improved on all cognitive tests (three tests for ages 4-6 years; 12 tests for ages 7+ years), whereas CTRLs only improved on one test. These data support the potential of multimodal training programs toward the overarching goal of improving cognitive performance in children with developmental and attentional difficulties.

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1. INTRODUCTION

A child's cognitive functioning is a reflection of his/her ability to perform higher-level mental processes that engage specific mechanisms associated with attention, learning, memory and reasoning. These cognitive functions allow children to interact with their environment in a goal-directed manner and shift behavior in response to changing environmental demands. Importantly, childhood cognitive skills are also thought to influence and be predictive of academic performance, including math, reading and writing [1-6].

Various aspects of cognitive functioning are known to be negatively affected in children with attention-deficit/hyperactivity disorder (ADHD) and even in children with subthreshold symptoms of ADHD that do not meet the full diagnostic criteria [7,8]. For example, children with ADHD show impairments in sustained attention, response inhibition, processing speed, and working memory, compared with typically developing children [8,9,10,11]. Studies suggest that it is the ADHD symptoms and underlying cognitive deficits — not comorbid conduct problems — that are at the root of poor academic performance commonly observed in children with attentional impairments [12,13,4].

Although genes exert substantial influence on the development of brain networks underlying cognitive processes such as attention [14], evidence shows that cognitive difficulties can be improved. For example, attention, working memory, and inhibitory control can be altered by training and practice, especially with certain types of video games, computer-based exercises, and repetition of specific tasks [15-19]. Attention has also been shown to improve following meditation training [20] and physical exercise [21]. And childhood cognitive development in general shows considerable positive effects from high-quality early education [22] and lifestyle factors such as nutrition [23]. Collectively, these studies show that multiple factors can be employed to enhance attention and other aspects of cognitive functioning, suggesting the importance of holistic integrated approaches to support cognitive development during childhood and adolescence [24].

The purpose of this study is to retrospectively review data on the cognitive task performance of children and adolescents with developmental and

cognitive difficulties, including attentional issues, before and after participation in an integrative, multimodal training program (Brain Balance® program) for 3 months. This group was compared to a control group that had all of the same underlying demographic and phenotypical features, but participated in the program for a significantly shorter duration of time. The Brain Balance program is a center-based program that aims to integrate sensory input and strengthen motor skills through regular frequency and duration of multimodal activities that target sensory functioning, motor skills, and exercises to address retained primitive reflexes, along with academic engagement, nutritional support, and complementary home-based exercises. The specific areas of cognitive performance examined before and after program participation were in concentration, verbal ability, memory, and reasoning.

2. METHODS

2.1 Design

Cognitive testing was administered before and after the Brain Balance program in order to look for changes in cognitive functioning associated with Brain Balance training, and to examine whether any particular sets of tests showed Brain Balance-specific improvement. Testing took place via the Cambridge Brain Sciences (CBS) web-based testing platform, which has been used for numerous large-scale studies of cognition [25-29]. At each testing point (before/after), participants completed a CBS assessment consisting of a collection of cognitive tests (see *Cognitive Test Batteries* for more detail). Participants completed one of two batteries depending on their age — participants aged 4-6 years completed a shorter and more age-appropriate set of cognitive tests than participants aged 7 years and older.

A subset of participants who completed a second CBS assessment *prior to completing* the Brain Balance program comprised a control group. That is, the only difference between the Brain Balance and control groups was the time between cognitive assessments (see participants below).

2.2 Inclusion Criteria

Prior to enrolling in the Brain Balance program, prospective students were assessed at Brain Balance centers by trained technicians who had

completed a progression of training in the centers' protocols. These technicians were required to pass all station certifications and be approved while being shadowed by a trainer. Students who were eligible for enrollment in the Brain Balance program did not have any known genetic disorders and needed to demonstrate a developmental readiness for the program. Readiness was defined as the ability to engage with instructors and follow a one-step direction, to attempt the tasks requested, and to continue to work throughout the duration of the assessment. Re-direction and repetition of instructions both visually and verbally were allowed in our definition of readiness. The students must also have tested below age-appropriate levels, as assessed by widely used functional tests measuring a student's abilities in the following categories: fine motor skills as assessed by the Purdue Peg Board [30]; body coordination, timing, and strength as assessed by the Presidential Fitness Test [31]; interaural asymmetry as assessed by the dichotic listening test [32]; and visual reading fluency as assessed by the Visagraph Reading Plus® tool [33]; as well as proprioception, balance, and vestibular function; auditory and visual processing; and eye coordination and movements. Enrolled children then participated in the Brain Balance program, as described in more detail in the Training Program section.

2.3 Participants

In the CBS database, cognitive test data were found for 12,317 Brain Balance participants who had been enrolled at Brain Balance center locations across the United States. After removing assessments that had missing test scores (incomplete assessments), 10,620 participants remained. Subjects with reported ages of younger than 3 years or older than 18 years were removed, leaving 9,914 datasets. Next, participants who completed the appropriate CBS battery (i.e., a 3-task battery for 4- to 6-year-olds and a 12-task battery for 7+ year-olds) more than once (total N = 598) were split into four groups: 1) a Brain Balance treatment group of 7+ year-olds (BB 7+; N = 374); 2) a control group of 7+ year-olds (CTRL 7+; N = 79); 3) a Brain Balance treatment group of 4- to 6-year-olds (BB 4-6; N = 104); and 4) a control group of 4- to 6-year-olds (CTRL 4-6; N = 41). Summaries of the age and gender composition for each group are shown in Table 1. Two-tailed (Welch's) *t*-tests indicated that age did not differ significantly between BB and CTRL groups for 4-

6 year-olds ($t_{(46,71)} = 0.52, p = 0.60$) or 7+ year-olds ($t_{(123,74)} = 0.04, p = 0.97$). Similarly, chi-squared tests revealed no differences in the proportion of males and females between groups for 4-6 year-olds ($\chi^2_{(1)} = 1.37, p = 0.24$) or 7+ year-olds ($\chi^2_{(1)} = 0.002, p = 0.96$). As expected, there was a significant difference between BB and CTRL groups, for both age groups, in the average time between the first and second assessments (4-6 years: $t_{(114,25)} = 24.50, p < 0.001$; 7+ years: $t_{(324,24)} = 41.00, p < 0.001$), such that BB participants had a much longer period of time between assessments (Table 1).

2.4 Training Program

The Brain Balance program consisted of three in-center sessions per week (for 3 months), with each session lasting 1 hour (45 minutes of sensorimotor stimulation and a 15-minute academic component focused on literacy and listening activities), along with other multimodal activities targeting the areas described in the list below. This training program protocol has previously been described in detail in Jackson & Robertson [34]. The program stations consisted of the following key pieces:

- Passive sensory stimulation in the form of tactile, olfactory, visual, and auditory stimulation [35].
- Exercises targeting primitive and postural reflexes [36].
- Core muscle exercises [37].
- Proprioceptive and balance training [38].
- Vestibular exercises, including rotational, translational, and anterior-to-posterior movements.
- Fine motor activities, including the palmar grasp reflex and the Purdue Peg Board [30].
- Rhythm and timing exercises, including whole-body coordination activities and use of the Interactive Metronome® [39].
- Activities that aim to enhance auditory and visual processing, as well as coordination and endurance of eye movements [40;41].

Parents were also asked to assist their children in completing daily exercises at home and were given nutritional guidance throughout the duration of the program. The home exercises consisted of 0-8 primitive reflexes, physical fitness activities (push-ups and sit-ups), and eye strengthening exercises.

Table 1. Age and gender breakdown and average duration between 1st and 2nd cognitive assessments, for each group

Group	N	Age (years)		Gender		Days between assessments	
		Mean	SD	Male %	Female %	Mean	SD
BB 7+	374	11	3	64.9	35.1	165.10	47.75
CTRL 7+	79	11	3.3	64.4	35.6	32.55	17.42
BB 4-6	104	5.4	0.7	79.5	20.5	160.95	47.98
CTRL 4-6	41	5.3	0.6	65.4	34.6	20.46	15.07

Abbreviations: BB, Brain Balance treatment group; CTRL, control; N, sample size; SD, standard deviation

2.5 Cognitive Test Batteries

Cognitive test batteries were administered at Brain Balance centers with trained staff members overseeing the process. All participants completed the initial tests prior to enrolling in the Brain Balance program. Upon completion of the program, participants returned to the Brain Balance center to complete the tests again, based on their schedule for availability. There were variations in the timing of test administration, which stemmed from: (1) participants' personal schedules for availability; and (2) some Brain Balance centers independently choosing when to administer tests.

Participants in the two age groups completed different, though overlapping, sets of cognitive tests. Participants in the younger age group (4-6 years) completed three CBS tasks, whereas participants in the older age group (7 years and older) completed 12 CBS tasks. Detailed descriptions of these tasks (including screenshots and test-retest reliability) can be found in the supplementary materials of Wild et al [29]. Briefly, the following were the tasks used: 1) Spatial Span (short-term memory); 2) Monkey Ladder (visuospatial working memory); 3) Paired Associates (episodic memory); 4) Token Search (working memory and strategy); 5) Odd One Out (deductive reasoning); 6) Rotations (mental rotation); 7) Feature Match (feature-based attention and concentration); 8) Spatial Planning (planning and executive function); 9) Interlocking Polygons (visuospatial processing); 10) Grammatical Reasoning (verbal reasoning); 11) Double Trouble (a modified Stroop task); and 12) Digit Span (verbal working memory). Each CBS task has a primary outcome measure that best reflects overall performance for that task [29], and our results are based on this measure unless otherwise specified. The younger group (4-6 years) completed a subset of these tasks — Paired Associates, Feature Match, and Spatial Span — that did not require any reading comprehension skills.

2.6 Data Analysis

Data were analyzed using custom code written in Python (v3.6.2, <https://www.python.org/>) using SciPy (v0.19.1), an open source collection of python modules for performing scientific and mathematical computing. Specific packages used included: NumPy (v1.13.1) to provide high-performance matrix and numeric calculation; Pandas (v0.20.3) for data organization, manipulation, and simple analyses; scikit-learn (v0.22.1) a machine learning toolbox that we used for data preprocessing and principal components analysis; and stats models (v0.8.0) for performing statistical tests (*t*-tests and ANOVAs). Figures were created using the Plotly for Python open source graphing library (v.4.7.1).

Before analysis, tests scores were filtered to remove outliers that were more than four standard deviations from the test mean. Cases were omitted on a per-test basis, such that the sample size could differ between tests. Next, test scores were standardized to have mean of 0.0 and standard deviation of 1.0 for each test. The parameters (i.e., the test means and standard deviations) used for this standardization step were derived from the larger dataset that included all subjects who had completed at least one assessment (N = 9,914 participants); only scores from participants' first assessment were used for this normative sample. Finally, difference scores were calculated for each participant, for each test, to quantify their change in test performance from the first to second CBS time point.

Differences scores were first analyzed using a mixed two-way ANOVA to examine the effects of group (BB, CTRL) and test (12 tests for age 7+ years, 3 tests for age 4-6 years) on changes in test performance. Levene's test was used to confirm homogeneity of variance for the between-subjects factor (group) at each level of the within-subjects factor (test). Mauchly's test was used to assess sphericity, and the

Greenhouse-Geiser correction was applied when this assumption was violated.

To investigate whether any CBS tests showed a significant improvement from the first to second assessment, one-tailed one-sample *t*-tests were used to test, for both BB and control groups, whether group mean difference scores were greater than zero. Similarly, we were specifically interested in which tests exhibited *greater* improvements for the BB compared to control participants; given this *a priori* hypothesis, one-tailed two-sample Welch's *t*-tests were used to compare mean difference scores between groups (i.e., the single tail specifically testing the hypothesis that difference scores were *greater* for the BB vs control group). Welch's *t*-test is robust to unequal sample sizes and/or variance and hence Type I errors [42,43], and therefore is a simple and appropriate statistical test for our data given the unequal sample sizes between groups. Statistical results were considered significant when $p < 0.05$ when corrected for multiple comparisons using the false discovery rate (FDR) method [44].

Finally, we performed a multivariate analysis to identify latent "component" scores in the 12-test battery and investigated whether these showed significant differences between groups over time. In addition to the primary outcome measure for each test, there are numerous other features (e.g., average reaction time, number of errors) that carry information about test performance. Principal component analysis (PCA) was used to reduce the 66 total features across all 12 CBS tests to a lesser number of components. The data used to train the PCA model were different from BB and CTRL subject scores (i.e., the BB/CTRL subjects with before/after assessments) to avoid circularity and bias in subsequent analyses of component scores; from the normative dataset of BB participants who completed at least one assessment ($N = 9,914$), those who completed the 12-test battery, had no missing data features ($N = 6,898$), and were not part of the before/after dataset ($N = 6,443$) were used to train the PCA model. PCA loadings were "whitened" so that resulting components scores were standardized ($M = 0$, $SD = 1.0$). Only 17 of the 66 components were retained for analysis, because these components had eigenvalues greater than 1.0 and they together explained 88% of the total variance in the dataset. In our analyses, components were ordered by decreasing variance explained (i.e., PC01 and PC17 indicate the first and 17th principal

components and explain the most and least variance, respectively). Component scores were then calculated for every BB 7+ and CTRL 7+ participant, for their first and second assessments, which were then converted to difference scores and analyzed similarly to the individual test scores. However, two-tailed tests were used to investigate changes in component scores given that the signs of PCA components (i.e., \pm directions) are arbitrary.

3. RESULTS

3.1 4- to 6-Year-Old Participants: Three-Test Battery Results

A two-way ANOVA on difference scores (i.e., the change in performance from first to second assessment) was first conducted to examine the relationship between Brain Balance programming and improvements in cognitive performance, with group membership (BB, CTRL) and cognitive test (three CBS tests) as factors. Levene's test indicated homogeneity of variance for the group factor across all levels of the test factor (all p 's > 0.05). We found a significant main effect of group ($F_{(1,121)} = 9.15$, $p < 0.005$, $\eta^2 = 0.027$), such that BB participants improved, in general, more than CTRL participants (Fig. 1). The main effect of cognitive test was not significant ($F_{(1.81, 218.78)} = 2.34$, $p = 0.1$), and neither was the interaction between group and test ($F_{(1.81, 218.78)} = 1.56$, $p = 0.22$).

We next performed one-sample *t*-tests on difference scores for each group and cognitive test to identify which tests showed significant improvement (i.e., difference scores greater than zero); results are reported in Table 2. We found that 4- to 6-year-old BB participants improved on all three tests — Spatial Span ($t_{(85)} = 3.58$, $p_{unc} < 0.001$, $p_{FDR} < 0.005$, $d = 0.39$), Feature Match ($t_{(85)} = 4.71$, $p_{unc} < 0.001$, $p_{FDR} < 0.001$, $d = 0.51$), and Paired Associates ($t_{(85)} = 2.17$, $p_{unc} < 0.05$, $p_{FDR} < 0.05$, $d = 0.23$) — whereas CTRL subjects improved only on Feature Match ($t_{(36)} = 2.33$, $p_{unc} < 0.05$, $p_{FDR} < 0.05$, $d = 0.38$).

Two-sample *t*-tests were then used to directly compare, for each CBS test, whether the magnitude of improvement seen in BB subjects was *greater* than the CTRL subjects' change in performance (Table 3; Fig. 1). This comparison was significant for both Spatial Span ($t_{(58.04)} = 1.93$, $p_{unc} < 0.05$, $p_{FDR} < 0.05$, $d = 0.39$) and Paired Associates ($t_{(70.89)} = 2.46$, $p_{unc} < 0.01$, $p_{FDR} = 0.05$, $d = 0.48$). These results suggest that the

significant main effect of group in the omnibus ANOVA (above) was driven by greater improvement for BB participants on these two tests.

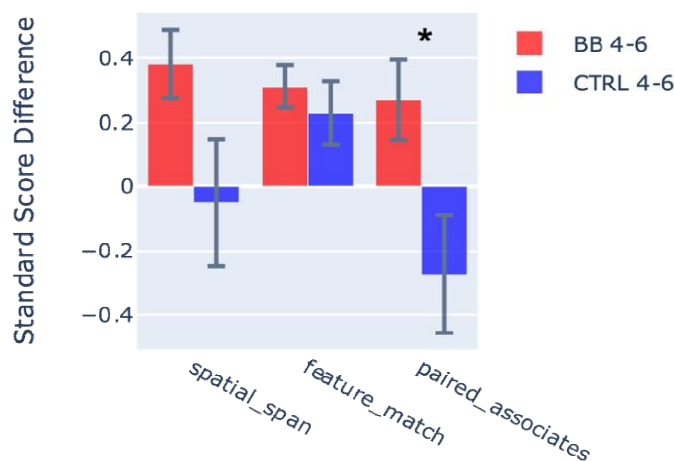


Fig. 1. The change in Cambridge Brain Sciences test performance from the first to second assessment for 4- to 6-year-old participants in the Brain Balance (red) and control (blue) groups. Test scores were first standardized (mean = 0; SD = 1.0 across the entire dataset) so that performance could be compared between tests. Bar height is the average change, from first to second assessment, across participants in each group, and error bars indicate the standard error of the mean. Bars greater than zero indicate improvement from first to second assessment. The asterisk shows a significant difference between groups ($p < 0.05$; FDR-corrected for multiple comparisons)

Abbreviations: BB, Brain Balance treatment group; CTRL, control

Table 2. Participants aged 4-6 years: Comparing cognitive test performance from the first to second assessment

Test	BB					CTRL				
	<i>t</i> -stat	df	p_{unc}	p_{FDR}	<i>d</i>	<i>t</i> -stat	df	p_{unc}	p_{FDR}	<i>d</i>
FM	4.71	85	< 0.001	< 0.001	0.51	2.33	36	0.013	0.039	0.38
PA	2.17	85	0.016	0.016	0.23	-1.50	36	0.929	0.929	-0.25
SS	3.58	85	< 0.001	< 0.001	0.39	-0.25	36	0.600	0.900	-0.04

NOTE: Bold rows indicate tests that showed significant improvement

Abbreviations: BB, Brain Balance treatment group; CTRL, control; SS, spatial span; FM, feature match; PA, paired associates; *t*-stat, *t*-statistic for the one-sample *t*-test comparing difference scores against zero; df, degrees of freedom; p_{unc} uncorrected one-tailed *p*-value; p_{FDR} *p*-value corrected for multiple comparisons; *d*, Cohen's *d*

Table 3. Participants aged 4-6 years: Comparing the change in performance on each cognitive test (from first to second assessment) between the Brain Balance and control groups

Test	<i>t</i> -stat	df	p_{unc}	p_{FDR}	<i>d</i>
FM	0.69	69.66	0.246	0.246	0.14
PA	2.46	70.89	0.008	0.024	0.48
SS	1.93	58.04	0.029	0.044	0.39

NOTE: Bold rows indicate tests that showed significantly greater improvement for the BB group

Abbreviations: FM, feature match; PA, paired associates; SS, spatial span; *t*-stat, Welch's *t*-statistic for the two-sample test comparing group mean differences in difference scores; df, Satterthwaite-corrected degrees of freedom; p_{unc} , uncorrected one-tailed *p*-value; p_{FDR} , *p*-value corrected for multiple comparisons; *d*, Cohen's *d* for Welch's test

3.2.7+ Year-Old Participants: 12-Test Battery Results

Again, we performed a two-way ANOVA on difference scores with group membership (BB, CTRL) and cognitive test (12 tests) as factors. Levene’s test for homogeneity of variance indicated no violations of this assumption (all corrected p ’s > 0.05). We observed a significant main effect of group ($F_{(1, 417)} = 15.87, p < 0.001, \eta^2 = 0.004$), such that BB participants (again) improved more than CTRL participants (Fig. 2). There was also a significant main effect of test ($F_{(10.42, 4344.35)} = 4.74, p < 0.001, \eta^2 = 0.01$), indicating that the amount of improvement differed between the cognitive tasks, but we did not explore this effect further because we were primarily interested in differences between groups. There was no significant interaction between group and CBS test ($F_{(10.42, 4344.35)} = 1.28, p = 0.23, \eta^2 = 0.003$).

One-sample t -tests of the difference scores for each group and cognitive test showed that BB participants improved on all 12 tests (see Table 4 for complete statistics). In contrast, the CTRL group improved only on Spatial Planning ($t_{(72)} = 4.62, p_{unc} < 0.001, p_{FDR} < 0.001, d = 0.54$).

Again, between-group comparisons were used to test whether the BB subjects improved more than the CTRL group (Table 5). Uncorrected statistics revealed significant group differences for six tests – Spatial Span, Digit Span, Token Search, Grammatical Reasoning, Odd One Out, and Rotations – but only three survived a correction for 12 comparisons: Digit Span ($t_{(98.64)} = 2.67, p_{unc} < 0.005, p_{FDR} = 0.05, d = 0.35$), Grammatical Reasoning ($t_{(100.24)} = 2.58, p_{unc} < 0.01, p_{FDR} = 0.05, d = 0.34$), and Odd One Out ($t_{(110.24)} = 2.40, p_{unc} < 0.01, p_{FDR} < 0.05, d = 0.30$). Taken together, these results indicate that the overall main effect of group in the ANOVA (i.e., greater overall cognitive improvement for BB participants) was due primarily to these three tests.

3.3 Multivariate Analysis

PCA of the larger normative dataset (i.e., sets of scores comprising all complete first assessments; $N = 6,443$) produced a model from which 17 components were retained. The first (largest) component explained 27% of the variance in the dataset, and cumulatively the 17 components explained 88% of the total variance.

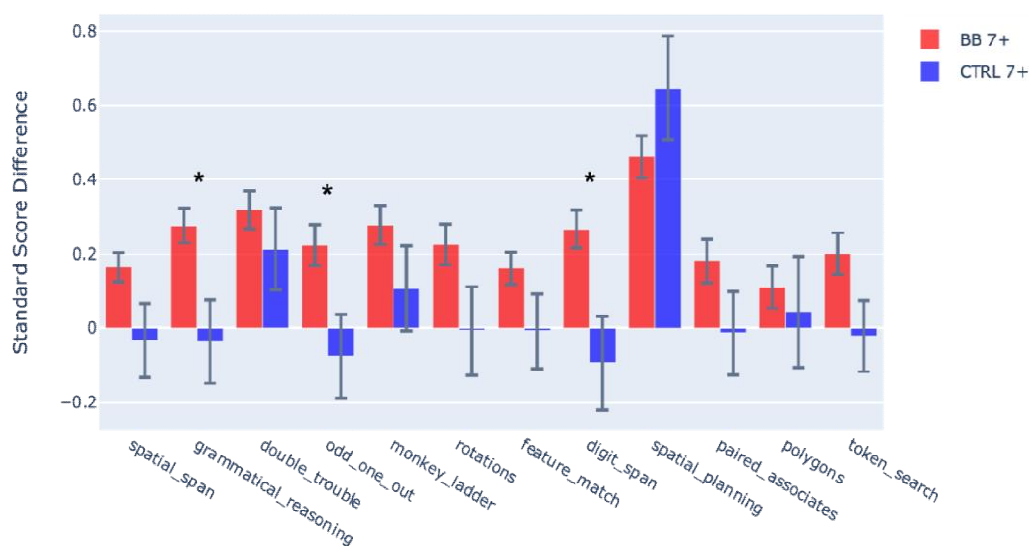


Fig. 2. The change in Cambridge Brain Sciences test performance from first to second assessment for participants aged 7 years and older (7+) in the Brain Balance (red) and control (blue) groups. Bar height indicates the average change from first to second assessment across participants in each group, and error bars show the standard error of the mean. Asterisks show significant differences between groups ($p < 0.05$, FDR-corrected for multiple comparisons)

Abbreviations: BB, Brain Balance treatment group; CTRL, control

Table 4. Participants aged 7 years and older: Comparing cognitive test performance from the first to second assessment

Test	BB 7+					CTRL 7+				
	t-stat	df	p_{unc}	p_{FDR}	d	t-stat	df	p_{unc}	p_{FDR}	d
DS	5.35	355	< 0.001	< 0.001	0.28	-0.75	74	0.771	0.771	-0.09
DT	6.36	354	< 0.001	< 0.001	0.34	1.95	74	0.027	0.164	0.23
FM	3.77	355	< 0.001	< 0.001	0.20	-0.08	74	0.532	0.755	-0.01
GR	6.02	355	< 0.001	< 0.001	0.32	-0.32	74	0.625	0.755	-0.04
ML	5.39	354	< 0.001	< 0.001	0.29	0.93	72	0.179	0.716	0.11
OOO	4.09	351	< 0.001	< 0.001	0.22	-0.68	73	0.749	0.771	-0.08
PA	3.12	355	0.001	0.001	0.17	-0.12	74	0.547	0.755	-0.01
PO	1.96	354	0.026	0.026	0.10	0.29	74	0.385	0.755	0.03
RO	4.14	355	< 0.001	< 0.001	0.22	-0.06	74	0.523	0.755	-0.01
SP	7.93	354	< 0.001	< 0.001	0.42	4.62	72	< 0.001	< 0.001	0.54
SS	4.20	355	< 0.001	< 0.001	0.22	-0.33	74	0.629	0.755	-0.04
TS	3.63	355	< 0.001	< 0.001	0.19	-0.22	74	0.588	0.755	-0.03

NOTE: Bold rows indicate tests that showed significant improvements, corrected for 12 comparisons, in each group

Abbreviations: BB, Brain Balance treatment group; CTRL, control; SS, spatial span; GR, grammatical reasoning; DT, digit span; OOO, odd one out; ML, monkey ladder; RO, rotations; FM, feature match; DS, digit span; SP, spatial planning; PA, paired associates; PO, polygons; TS, token search; t-stat = t-statistic for the one-sample t-test comparing difference scores against zero; df = degrees of freedom; p_{unc} = uncorrected one-tailed p-value; p_{FDR} = p-value corrected for multiple comparisons; d = Cohen's d

Table 5. Participants aged 7 years and older: Comparing the change in performance on each cognitive test (from first to second assessment) between the Brain Balance and control groups

Test	t-stat	df	p_{unc}	p_{FDR}	d
DS	2.67	98.64	0.004	0.034	0.35
DT	0.87	107.37	0.192	0.230	0.11
FM	1.55	102.71	0.062	0.095	0.20
GR	2.58	100.24	0.006	0.034	0.34
ML	1.35	102.66	0.090	0.120	0.17
OOO	2.40	110.24	0.009	0.036	0.30
PA	1.54	116.95	0.063	0.095	0.19
PO	0.42	96.27	0.339	0.370	0.06
RO	1.76	106.44	0.041	0.082	0.22
SP	-1.23	98.33	0.889	0.889	-0.16
SS	1.85	98.33	0.034	0.081	0.25
TS	2.02	129.32	0.023	0.069	0.24

NOTE: Bold rows indicate tests that had significantly greater improvement for BB participants, corrected for multiple comparisons ($p_{FDR} < 0.05$)

Abbreviations: SS, spatial span; GR, grammatical reasoning; DT, digit span; OOO, odd one out; ML, monkey ladder; RO, rotations; FM, feature match; DS, digit span; SP, spatial planning; PA, paired associates; PO, polygons; TS, token search; t-stat = Welch's t-statistic for the two-sample test comparing group mean differences in difference scores; df = Satterthwaite-corrected degrees of freedom; p_{unc} = uncorrected one-tailed p-value; p_{FDR} = p-value corrected for multiple comparisons; d = Cohen's d for Welch's test

Analyses of component difference scores (representing the change in performance, for each component, from the first to second assessment) showed that the BB 7+ group had significant changes in performance on six measures (Fig. 3; also see Table S1 and Fig. S1 in Supplementary Material): PC01 ($t_{(313)} = 16.34$, $p_{unc} < 0.001$, $p_{FDR} < 0.001$, $d = 0.92$); PC03 ($t_{(313)} = 3.42$, $p_{unc} = 0.001$, $p_{FDR} < 0.005$, $d = 0.19$); PC10 ($t_{(313)} = 3.07$, $p_{unc} < 0.005$, $p_{FDR} < 0.01$, $d = 0.17$); PC11 ($t_{(313)} = 4.25$, $p_{unc} < .001$, $p_{FDR} < 0.001$, $d = 0.24$); PC13 ($t_{(313)} = 3.07$, $p_{unc} < 0.005$, $p_{FDR} < 0.05$, $d = 0.16$); and PC15 ($t_{(313)} = -3.01$, $p_{unc} < 0.005$, $p_{FDR} < 0.05$, $d = -0.17$). The CTRL 7+ group, on the other hand, showed significant change on only two components (Fig. 3; also see

Table S1 in Supplementary Material): PC11 ($t_{(66)} = 3.48, p_{unc} < 0.001, p_{FDR} < 0.05, d = 0.42$) and PC15 ($t_{(66)} = -3.14, p_{unc} < 0.005, p_{FDR} < 0.05, d = 0.25$). Importantly, we found that the change in performance differed significantly between groups for only the first principal component: PC01 ($t_{(81.50)} = 4.19, p_{unc} < 0.001, p_{FDR} = 0.001$) (Fig. 3; also see Table S2 in Supplementary Material). As a consequence of the PCA scores being standardized, this means they improved by 0.42 standard deviations (Cohen's $d = 0.42$) which corresponds to a small-to-medium effect size, according to Cohen's criteria [45].

4. DISCUSSION

The transition from childhood through adolescence into adulthood represents a window of opportunities for the acquisition of complex higher-order cognitive abilities and for the corresponding refinements in brain structure and function supporting these abilities [46,47]. Evidence suggests that cognitive abilities during development can be improved through various types of training and practice [15,16,17,18,20,21]. In the present study, children and adolescents with developmental and cognitive difficulties, including attentional issues, showed improvements in aspects of cognitive task performance following participation in the Brain Balance program, a comprehensive multimodal training program. The improvements in cognitive performance were observed in all

age groups examined, ranging from 4 to 17 years.

In children aged 4-6 years, we measured performance on three select tasks of cognition that a child without letter or number recognition would be capable of completing. These children showed significant improvements on all three tasks — Spatial Span, Feature Match, and Paired Associates — after program participation, compared to their own baseline performance prior to program initiation. In the control group, some participation in the program (on average 27 days) was sufficient to produce a significant improvement from pre- to post-program, but on only one task — Feature Match — which measures concentration and attention.

The results for the 4- to 6-year-old group also showed that the Brain Balance group improved more overall in cognitive performance than the control group. This overall improvement stemmed from a significant difference between the groups in performance on two tests in particular, where the Brain Balance group showed significantly greater performance on Spatial Span and Paired Associates compared to controls. Spatial Span is thought to measure planning and executive function, and Paired Associates is thought to measure episodic memory, the ability to remember and recall events paired with the context (e.g., particular

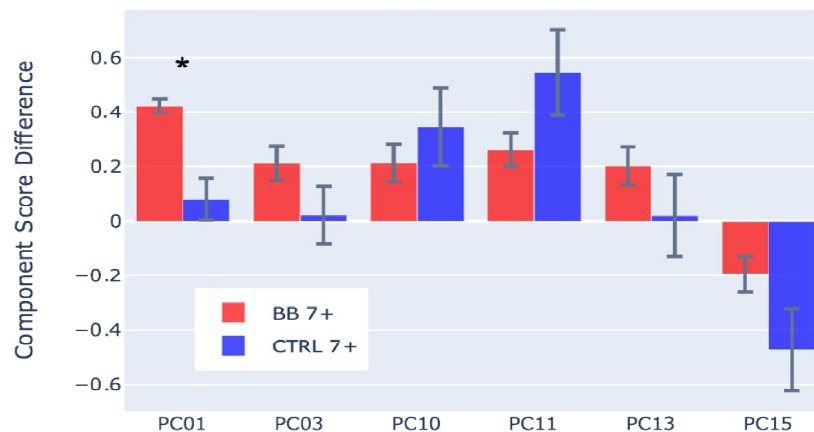


Fig. 3. The change in principal component analysis scores from first to second assessment for participants aged 7 years and older (7+) in the Brain Balance (red) and control (blue) groups. Only components that showed a significant difference from zero for the BB 7+ group are shown. The asterisk shows significant differences between groups ($p < 0.05$, FDR-corrected for multiple comparisons)

Abbreviations: BB, Brain Balance treatment group; CTRL, control; PC, principal component

times and places) in which they occurred [48]. Episodic memory has been argued to be involved both in the capacity to retrieve personal past experiences and to foresee future scenarios, which develops substantially between 3 and 5 years old [49].

In children aged 7+ years, we measured performance on a more extensive battery that included 12 cognitive tests assessing various areas of memory, reasoning, verbal ability, and concentration. Like the participants in the 4-6 age group, those in the 7+ age group who completed the Brain Balance program demonstrated significant improvement on all tests from pre- to post-program. In contrast, the control group improved on only one test (spatial planning). The results in children aged 7+ years were similar to those in the 4-6 age group in that they also showed significantly greater overall cognitive improvement than the control group. This group difference between the Brain Balance group and the control group was attributable primarily to significantly greater improvement on three tests in particular: Grammatical Reasoning (which measures verbal reasoning), Digit Span (which measures verbal short-term memory), and Token Search (which measures working memory).

A principal components analysis performed on the 12-test data from the 7+ age group largely corroborated aspects of the abovementioned results, in that children in the Brain Balance group significantly improved on a greater number of components from pre- to post-program than did the control group. Further analysis showed that pre- and post-program improvements in cognitive performance differed significantly between the Brain Balance group and the control group for one principal component in particular, PC01. The pattern of these results indicated that the group difference was driven by the fact that Brain Balance participants exhibited a large and significant improvement in this score whereas control participants did not. Although components can be difficult to interpret when many variables load on them, PC01 is easily explainable: the loadings were positive for all score features that increased with better performance (e.g., number of items correct) and were negative for score features that increased with worse performance (e.g., number of errors, or reaction times). Therefore, PC01 can be interpreted as a measure of overall performance across the battery of 12 cognitive tests.

Collectively, the results show that children in both the younger and older age groups who

completed the Brain Balance program displayed significant improvements in cognitive task performance, particularly in the areas of memory (episodic, short-term, and working memory) and reasoning. Interestingly, significant improvements in performance were also observed on some cognitive tasks even in the control groups that participated in the program for less time — for example, on tasks measuring attention and spatial planning. These results may reflect the capacity of certain aspects of cognitive performance to change in response to a shorter time period of training than other areas that may require a longer duration of training before significant improvements can be seen. However, while both the Brain Balance and control groups showed improvement, the present findings suggest that a longer duration of program participation (3 months) may be more efficacious in producing cognitive gains than a shorter duration of participation (on average for 27 days). Alternatively, improvements in the control groups might reflect a practice effect (i.e., better performance at the tests the second time around). The Brain Balance groups, however, exhibited improvements that were greater than those in the control groups, suggesting that their improvements are not due to just practice, but rather to specific training aspects related to the Brain Balance program.

The participants in the present study all presented with developmental and cognitive difficulties (including inattention) prior to program enrollment. The areas of cognitive performance that improved after Brain Balance program participation are some of the same cognitive areas reported to be impaired in children with ADHD compared to typically developing children [50,51,52]. Conventional first-line treatments for ADHD include pharmacological treatment with central nervous system stimulants; however, the number of non responders, the risk of adverse effects, medication adherence issues, and potential consequences on the developing brain call for more alternatives or adjuncts to pharmacological treatment in order to optimize functioning [53,54]. Although nonpharmacological alternatives may not be as effective for targeting the core ADHD symptoms especially in more severe cases, they may effectively address ADHD-related impairments, such as working memory deficits [55]. Consistent participation in training programs, such as the Brain Balance program, may serve as a potential nonpharmacologic alternative or adjunct to supporting cognitive development and

associated academic performance in children with cognitive difficulties and attentional issues.

In this study, significant cognitive improvements resulted from participation in a multimodal combination of many intervention-based activities. These findings will form the basis for a number of future controlled trials that could better distinguish the individual aspects of Brain Balance training that are most effective for improving cognitive performance and other functional outcomes. For example, it is plausible that the cognitive improvements observed in this study may have occurred, in part, through an indirect effect on improvements in sensory regulation and/or in motor skills. There is a significant positive correlation between the number of ADHD traits and the frequency of reported sensory processing problems [56], and children with ADHD exhibit more sensory processing problems than children without ADHD [57,58,59], suggesting that sensory difficulties could be part of the ADHD phenotype [60]. Interestingly, adding a sensory-stimulation intervention to psychostimulant treatment in children with ADHD produces significant gains in reading recognition and comprehension and in math calculations and problem solving [61]. In addition, both fine and gross motor skills are associated with better performance in various cognitive domains, including sustained attention, spatial working memory, processing speed, and episodic and semantic memory, which, in turn, are all associated with better performance in math and reading comprehension [62,63]. Because a substantial portion of the Brain Balance program targets sensorimotor functioning, improvements in sensorimotor areas might in turn also improve cognitive skills in children with developmental and attentional difficulties.

Ideally, any cognitive gains achieved after Brain Balance program participation would continue to be maintained beyond the 3 months of participation. If these skills are indeed maintained, the present findings could potentially have important implications for longer term performance in academic settings. Although the present study did not follow up with participants at additional later time points after program completion, there is evidence suggesting that cognitive gains from training programs can have lasting effects in children [64,65]. Future studies will need to follow up on whether the observed effects on cognitive task performance endure beyond completion of the program.

The present study's inclusion of a control group that participated for less time than the Brain Balance treatment group was helpful in potentially revealing the specific cognitive areas that improve with shorter versus longer duration of program participation. However, the lack of a control group that is entirely nonparticipating necessitates caution in interpretation of the findings. A comparison of program participants with nonparticipant controls will be important to making more complete conclusions on the effects of the Brain Balance program on cognitive functioning in future studies.

5. CONCLUSION

In this retrospective review of cognitive test results from the Cambridge Brain Sciences database, we found that participants of the Brain Balance program showed significant overall performance on specific tests of memory, reasoning, verbal ability, and concentration. The present findings point to the potential of nonpharmacologic training programs, such as the Brain Balance program, in significantly improving aspects of cognitive performance in children and adolescents with developmental and attentional issues, especially programs that comprehensively target and integrate multiple developmental areas.

DISCLAIMER

The products used for this research are commonly and predominantly used products in our area of research and country. There is absolutely no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for any litigation but for the advancement of knowledge.

CONSENT AND ETHICAL APPROVAL

Approval for a retrospective data review was granted by an institutional review board (IRB) at Advarra (Columbia, Maryland, USA), an independent organization accredited by the U.S. Office for Human Research Protections and the Association for the Accreditation of Human Research Protection Programs. The Advarra IRB determined that this retrospective data review met the requirements for exemption from IRB oversight, according to the Department of Health and Human Services regulations found at 45 CFR 46.104(d)(4). In addition, for general participation in the Brain Balance program,

informed parental consent was obtained for any students prior to enrollment.

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COMPETING INTERESTS

R. Jackson works for Brain Balance Achievement Centers but has no financial stake in the outcome of this study or in the publication of the results. C.J. Wild provides consulting services for Cambridge Brain Sciences.

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