A Randomized, Double-Blind, Placebo Controlled, Parallel Group, Efficacy Study of Alpha BRAIN® Administered Orally

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Background

Alpha BRAIN® is a nootropic supplement that purports to enhance cognitive functioning. Several of the naturally occurring compounds in Alpha BRAIN® have cholinesterase inhibiting properties and thus could prove beneficial in individuals with subjective memory complains or objective cognitive impairment due to Alzheimer's disease or other cognitive disorders. The goal of this preliminary study was to investigate the efficacy of this self-described cognitive enhancing nootropic on cognitive functioning in a group of healthy adults by utilizing a randomized, double-blind, placebo controlled design.

Participants and Methods

A total of 63-treatment naïve individuals completed this randomized, double-blind, placebo controlled trial. All participants completed a two-week placebo run-in before receiving either active product, Alpha BRAIN® (**n=30**) or new placebo (**n=33**). Participants then followed the manufactures recommended instructions for use for six weeks. Following their placebo run-in, participants undertook a battery of neuropsychological tests before being randomized, and again approximately six weeks later at study completion. Primary outcome measures included neuropsychological tests from the WMS-IV, DKEFS, CVLT-II, Trails A & B and PSAT as well as measures of wakefulness and dreams.

Results

Bivariate analysis indicated no significant differences between groups on any demographic variables and both groups demonstrated excellent supplement adherence (**> 90%**). Following the two-week placebo run-in, no significant differences were found between groups on any cognitive measure . At six weeks, significant improvement was noted in tasks of delayed verbal recall (**CVLT Long Delay Recall (*t* [61] = 2.48, *p* = 0.01**)) and executive functioning (Trails Making Test **(*t* [61] = -1.96, *p* = 0.05**)) for the Alpha BRAIN® group compared to placebo. Both groups demonstrated overall improvement on neuropsychological tests between time points. A mixed model repeated measures analysis of variance (ANOVA) was performed for each cognitive outcome measure. Results of the ANOVA indicated a significant test-by-treatment interaction for CVLT Long Delay (**F [1,61] = 4.07, *p* = 0.04**) with the Alpha BRAIN® group demonstrating significantly improved performance over placebo control (see Figure 3). No other group effects reached statistical significance.

Conclusions

The use of Alpha BRAIN® for 6-weeks significantly improved recent verbal memory and executive function when compared with controls, in a group of healthy adults aged 18-35. Results of this trial merit further study toward the

Figure 1: Breakdown of the Sample

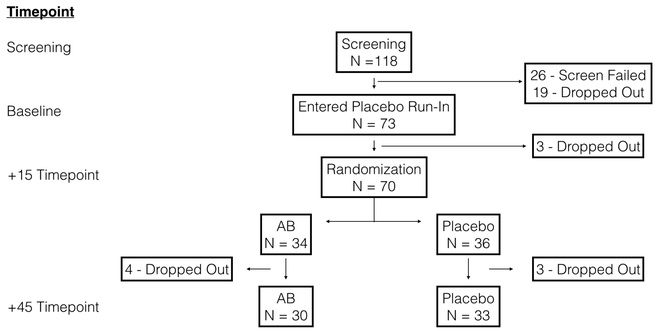

Figure2: Test-by-Treatment Interaction for CVLT Long Delay

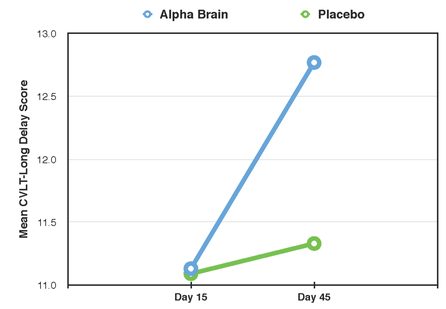

Table 1: Demographic Characteristics of the Study Sample

	Total n = 63	AlphaBrain n = 30	Placebo n = 33
Age at Baseline	M = 23.67	M = 24.43	M = 22.97
Estimated IQ (WTAR)	M = 110.19	M = 110.73	M = 109.69
MMSE Score	M = 29.48	M = 29.50	M = 29.45
Gender	% (n)	% (n)	% (n)
Male	44.4 (28)	46.7 (14)	42.4 (14)
Female	55.6 (35)	53.3 (16)	57.6 (19)
Level of Education			
Less then High School	3.2 (2)	6.7 (2)	0.0 (0)
High School	19.0 (12)	20.0 (6)	18.2 (6)
Associates Degree	7.9 (5)	13.3 (4)	3.0 (1)
Current College Student	50.8 (32)	40.0 (12)	60.6 (20)
Batchelors Degree	15.9 (10)	20.0 (6)	12.1 (4)
Graduate Degree	3.2 (2)	0.0 (0)	6.1 (2)
Race / Ethnicity			
White (Not Hispanic)	69.8 (44)	63.3 (19)	75.8 (25)
Black / African American	4.8 (3)	6.7 (2)	3.0 (1)
Hispanic	11.1 (7)	6.7 (2)	15.2 (5)
Asian / Pacific Islander	7.9 (5)	10.0 (3)	6.1 (2)
American Indian	1.6 (1)	3.3 (1)	0.0 (0)
Mixed / Multiple	4.8 (3)	10.0 (3)	0.0 (0)

Table 2: Individual Neuropsychological Test Raw Scores by Time Point and Group

	+15		+45	
Outcome Measure	**AB n = 30**	**Placebo n = 33**	**AB n = 30**	**Placebo n = 33**
Logical Memory I Total	M = 27.27 SD = 6.13	M = 26.00 SD = 6.54	M = 29.57 SD = 7.24	M = 28.57 SD = 3.20
Logical Memory II Total	M = 23.67 SD = 6.55	M = 22.88 SD = 6.21	M = 28.57 SD = 9.99	M = 29.45 SD = 6.87
BVMT Trial I	M = 8.63 SD = 2.78	M = 8.55 SD = 2.27	M = 9.20 SD = 3.03	M = 10.24 SD = 2.20
BVMT Trial II	M = 10.90 SD = 1.51	M = 11.09 SD = 1.28	M = 10.93 SD= 2.01	M = 11.42 SD = 1.75
BVMT Trial III	M = 11.40 SD = 1.07	M = 11.33 SD = 1.36	M = 11.50 SD = 1.13	M = 11.70 SD = 1.05
BVMT Total	M = 31.10 SD = 4.83	M = 31.00 SD = 4.21	M = 31.37 SD = 5.68	M = 33.36 SD = 4.68
BVMT Delay	M =11.33 SD = 1.12	M = 11.30 SD = 1.21	M = 11.37 SD = 1.21	M = 11.58 SD = 1.03
F Total	M = 14.10 SD = 4.11	M = 14.03 SD = 4.01	M = 17.77 SD = 5.63	M = 17.48 SD= 4.57
A Total	M = 13.53 SD = 3.90	M = 12.91 SD = 3.61	M = 14.00 SD = 4.88	M = 14.82 SD = 4.83
S Total	M = 16.13 SD = 3.73	M = 16.27 SD = 4.30	M = 14.63 SD = 4.18	M = 14.55 SD = 4.43
FAS Total	M = 43.77 SD = 5.30	M = 42.15 SD = 10.1	M = 46.40 SD = 12.9	M = 46.82 SD 11.21
Animals Total	M = 24.63 SD = 5.30	M = 24.55 SD = 5.46	M = 22.27 SD = 5.93	M = 22.58 SD = 4.22
Switching Total	M = 15.50 SD = 2.78	M = 15.09 SD = 2.79	M = 14.17 SD = 3.39	M = 15.30 SD = 3.00
Symbol Span	M = 30.23 SD = 7.07	M = 29.85 SD = 9.14	M = 31.97 SD = 9.11	M = 30.30 SD =6.88
Digit Symbol Coding	M = 58.50 SD = 12.55	M = 59.64 SD = 9.93	M = 58.23 SD = 8.55	M = 64.12 SD = 1.49
Trails A	M = 22.87 SD = 8.78	M = 22.39 SD = 5.69	M = 20.70 SD = 6.57	M = 20.58 SD = 6.80
Trails B	M = 54.90 SD = 17.5	M = 62.55 SD = 21.6	***M = 43.33 SD =15.1**	***M = 51.21 SD =16.4**
20 Questions Total Score	M = 25.40 SD = 5.21	M = 25.82 SD = 5.37	M = 26.30 SD = 4.42	M = 25.00 SD = 5.33
20 Questions Ach. Score	M = 16.60 SD = 3.43	M = 16.33 SD = 2.45	M = 15.73 SD = 2.16	M = 16.03 SD = 2.50
Stroop Inhibition	M = 44.23 SD = 9.00	M = 44.64 SD = 10.7	M = 42.63 SD 7.97	M = 40.55 SD = 8.26
Stroop Switching	M = 54.17 SD = 13.6	M = 52.58 SD = 9.61	M = 51.17 SD = 13.8	M = 48.79 = 12.97
CVLT Total Score	M = 43.76 SD = 9.97	M = 43.21 SD = 10.1	M = 46.40 SD = 12.9	M = 46.84 SD = 11.2
CVLT Short Delay	M = 11.27 SD = 2.37	M = 11.39 SD = 2.17	M = 11.83 SD = 2.94	M = 12.39 SD =1.96
CVLT Long Delay	M = 11.13 SD = 2.60	M = 11.09 SD = 3.18	***M = 12.77 SD = 2.2**	***M = 11.33 SD = 2.3**
PSAT Trial I	M = 38.33 SD = 13.18	M = 39.15 SD = 11.8	M = 43.30 SD = 13.0	M = 43.33 SD = 10.3
PSAT Trial II	M = 28.83 SD = 10.78	M = 28.64 SD = 9.04	M = 30.03 SD = 13.1	M = 32.12 SD = 9.23

* < .05