CLINICAL STUDY REPORT SUMMARY

Evaluation of a Vitamin/Nutraceutical Formulation Designed to Support and Maintain Memory, Concentration and Focus in Healthy Adults

Sponsor:	Factor Nutrition Labs, LLC. 865 Spring Street Westbrook, ME 04092
Protocol Number:	VNF-001
Investigational Product:	FOCUSfactor®
Report Date:	August 19, 2011
Conclusion:	The study shows that FOCUSfactor improves memory, concentration and attention (e.g., focus) in healthy adults following six weeks of administration. The improvement in memory seen in this study for individuals who received FOCUSfactor is comparable to a decrease of 20 years in cognitive aging.

This study was conducted in compliance with all applicable country requirements for the conduct of clinical studies, including those outlined by the International Conference on Harmonization, Consolidated Guidelines on Good Clinical Practices, and the Food and Drug Administration.

1. SUMMARY OF RESULTS

The present study demonstrates that, compared to placebo, FOCUSfactor improves abilities referred to as memory (i.e., short term memory), attention (e.g., focus), concentration and working memory in healthy adults. Following 6 weeks of treatment, subjects who received FOCUSfactor had a mean increase in recall of 6.5 words compared to 4.5 words for those who received placebo ($t = -4.32$, $df = 87$, $p < 0.001$). The total words recalled over Trials 1-5 following 6 weeks of treatment (corrected for baseline score) was 51.9 words for subjects receiving FOCUSfactor compared to 49.7 words for subjects receiving placebo ($t = -2.98$, $df = 87$; $p = 0.002$). The significant effect on RAVLT Sum 1-5 supports the hypothesis that FOCUSfactor improves memory, attention (e.g. focus), and concentration.

The FOCUSfactor group improved more than the placebo group for each of the RAVLT learning and recall trials, and a statistical analysis of the individual acquisition trials of the RAVLT shows significant improvement ($p < 0.001$) for FOCUSfactor compared to placebo for the first acquisition trial (RAVLT1) and a trend for improvement for the second acquisition trial ($p = 0.11$). This indicates that the improvement in the RAVLT Sum 1-5 may largely be due to its beneficial impact on working memory. This is further supported by analysis of the CogScreen results which show significant improvement with FOCUSfactor compared to placebo on a validated measure of working memory (Dual Task Test Previous Number Alone; $t = 1.89$, $df = 87$; $p = 0.031$). Accuracy in recalling previously presented digits improved by 3.7% for subjects receiving FOCUSfactor, whereas accuracy declined by 1.2% for those who received placebo. Correlations between CogScreen and the RAVLT indicate that performance on the first two RAVLT acquisition trials (RAVLT1 and RAVLT2) is mostly determined by working memory and information processing speed.

To better understand the magnitude of the improvement seen with FOCUSfactor, the changes in RAVLT performance seen in this trial can be viewed in terms of the effects that normal aging has on RAVLT performance. The average score obtained for RAVLT Sum Trials 1-5 for subjects who received placebo in the current study is comparable to the average score obtained by individuals in the 30-39 year age group (RAVLT Sum Trials 1-5 = 48.6 ± 10.3) (Strauss 2006b). By comparison, the score obtained by subjects who received FOCUSfactor is comparable to the average score obtained by individuals in the 20-29 year age group (RAVLT Sum Trials 1-5 = 52.2 ± 7.3). Furthermore, the difference of 2 points found in total recall score in this trial is comparable to a 20 year age difference. For example, the average RAVLT Sum Trials 1-5 score for age 30-39 is 48.6 and the average score for age 50-59 is 46.4. Thus, it is readily apparent that the magnitude of the difference in test performance between subjects receiving FOCUSfactor and those receiving placebo is clinically meaningful.

The results found for FOCUSfactor in the current study can also be compared to those found in a similar study designed to assess the effects of the aquatic plant Bacopa, an herbal agent which has been used in Ayurvedic medicine to enhance memory and which is contained in FOCUSfactor (Morgan 2010). The investigators found significant improvement ($p = 0.011$) in RAVLT Sum Trials 1-5 scores in older adults (mean age 65). For subjects receiving Bacopa, the total RAVLT score improved by 2.9 words (from 41.4 to 44.3) from Baseline to Week 12, and for subjects who received placebo the total RAVLT score declined by 1.8 words (from 41.2 to

39.4). By comparison, in the current study, subjects receiving FOCUSfactor for six weeks had an average increase of 6.5 words, whereas the placebo subjects had an increase of 4.5 words.

While the RAVLT Sum Trials 1-5 analysis shows significant efficacy for memory generally, the impact of FOCUSfactor was most evident on measures of working memory. Working memory is described as "a limited-capacity store for retaining information over the short term (seconds to 1-2 minutes) and for performing mental operations on this store" (Strauss 2006a). For the RAVLT this is best demonstrated by the initial, first trial recall of the word list that has been read by the examiner. The words are in a temporary, mental storage.

Working memory enables individuals to keep several pieces of information active while trying to do something with them. Working memory is essential to the ability to perform multiple tasks at once – or to divide attention. Memory performance is also dependent upon working memory. As stated by Torkel Klingberg, MD, PhD, an assistant cognitive neuroscience professor at the Karolinska Institute in Sweden. (Dingfelder 2005):

> "People may be able to remember a nearly infinite number of facts, but only a handful of items--held in working memory--can be accessed and considered at any given moment. It's the reason why a person might forget to buy an item or two on a mental grocery list, or why most people have difficulty adding together large numbers. In fact, working memory could be the basis for general intelligence and reasoning: Those who can hold many items in their mind may be well equipped to consider different angles of a complex problem simultaneously.
>
> If psychologists could help people expand their working-memory capacity or make it function more efficiently, everyone could benefit, from chess masters to learning-disabled children."

In addition to these efficacy findings, the study results demonstrate that FOCUSfactor was very well tolerated. Subjects receiving placebo reported more adverse events and received more concomitant medications than those receiving FOCUSfactor, and no serious adverse events were reported.

2. ETHICS

2.1 Institutional Review Board

The protocol was reviewed by an independent Institutional Review Board (IRB); Chesapeake Research Review, Inc., 7063 Columbia Gateway Drive, Suite 110, Columbia, MD 21046 (IRB Chair: Joy Cabagnaro, Ph.D.). Prior to the initiation of the clinical trial, the investigative site obtained written and dated approval by the IRB for the protocol, the informed consent form, advertisements for the study, and any written information given to the subjects.

2.2 Ethical Conduct

The study was conducted in compliance with Institutional Review Board (IRB), informed consent regulations, and International Conference on Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. In addition, all local regulatory requirements were adhered to, in particular those which afforded greater protection to the safety of the trial participants.

3. INVESTIGATORS AND STUDY STRUCTURE

The study was sponsored by Factor Nutrition Labs, LLC and was conducted at Cognitive Research Corporation (CRC), 200 Central Avenue, Suite 1230, Saint Petersburg, FL 33701. The sponsor in consultation with CRC was responsible for study design including selection of dose, eligibility criteria, efficacy and safety assessments, and vitamin/nutraceutical supply. CRC, a contract research organization (CRO), was responsible for data collection, database preparation, overall project management, site monitoring, data management, statistical analyses, and preparation of the final clinical study report.

4. INVESTIGATIONAL PLAN

4.1 Overall Study Design and Plan

This was a single-center, randomized, double-blind, placebo-controlled, parallel group study to evaluate the effect of a Vitamin/Nutraceutical Formulation (VNF), marketed under the name FOCUSfactor®, on memory, concentration, and focus in healthy adults. Study endpoints included: (1) Sum of 5 acquisition trials on the Rey Auditory Verbal Learning Test (RAVLT) for the modified ITT (mITT) at Week 6, (2) Delayed Recall Trial Score (RAVLT) for the mITT at Week 6, (3) individual RAVLT Trials 1-5, List B, Short and Long Delay recall for the mITT population, (4) RAVLT Retention (Delayed Recall ÷ Trial 5) for the mITT population, and (5) CogScreen subtest scores for the mITT population.

4.2 Selection of Study Population

The study was conducted in normal, healthy, male and female subjects. Subjects were required to meet the following inclusion criteria and not meet any of the exclusion critiera as follows:
Inclusion Criteria:

- Age 18-65 years (inclusive)
- Fluent in English
- Good physical health based on review of medical history
- Score $\geq$ 26 on the Mini Mental State Exam (MMSE)
- Score $\geq 16^{th}$ percentile (for age) on RAVLT Sum of 5 acquisition trials and delayed recall score at screening and baseline (floor effect)
- Score $\leq 85^{th}$ percentile (for age) on RAVLT Sum of 5 acquisition trials and delayed recall score at screening and baseline (ceiling effect)
- Adequate visual and auditory acuity and cognitive ability to complete the assessments and capable of understanding and following instructions

- Willing to maintain normal activity level/exercise routine
- Willing and able to comply with all requirements defined within this protocol

Exclusion Criteria:

- Depression score of ≥9 on Geriatric Depression Scale
- Lactose intolerance or history of allergies, adverse reactions, or intolerance to any compound contained in the vitamin/nutraceutical preparation
- Current evidence of any medical or psychiatric disorder that could significantly influence cognition
- Current evidence of hearing impairment or other information processing impairment
- Unusual dietary habits (e.g. South Beach or Atkins diet, Pritikin diet)
- History of or current inflammation of the GI system, such as irritable/inflammatory bowel disease, diverticular disease, gastric or duodenal ulcers, and severe GERD (requiring daily medication)
- History of seizure disorder (with the exception of isolated, one-time episodes, e.g. febrile or infant)
- Current use of any medication that is contraindicated for use with the study compound
- Current use of hormone replacement therapy, therapy for benign prostatic hyperplasia, vitamin or mineral supplements, or DHA, unless stable for the last 30 days with no changes in dosages expected during the study
- Current use of SAM-e, citicholine, huperzine, gotukola or alpha tocopherol > 400 IU
- Current use or use within 14 days of randomization of any medication or dietary supplement taken to improve cognition. This includes all cholinesterase inhibitors, memantine, as well as dietary supplements such as ginkgo biloba, phosphatidylserine, vinpocetine, etc.
- Current use or use within 14 days of randomization of other medications that have adverse effects on cognitive performance performance (e.g. anticholinergic medications, sedating antihistamines, decongestant sympathomimetics, benzodiazepines, tricyclic anti-depressants).
- Concurrent chronic or acute illness (such as allergic rhinitis or severe cold) or other condition that, in the Investigator's opinion, might preclude the subject from completing the study or would not be in the best interest of the subject. This would include any significant illness or unstable medical condition that could lead to difficulty complying with the protocol.
- Participation in an investigational study or received an investigational drug within the past 28 days.
- Pregnant or lactating women or women planning to become pregnant during the study.
- Judgment by the Investigator that individual is unsuitable for enrollment in this study for any reason.

4.3 Study Treatments

Subjects were administered one of two treatments:

- Placebo taken as four tablets once daily. Placebo tablets were identical in appearance to FOCUSfactor.

- FOCUSfactor taken as four tablets once daily.

4.4 Method of Assigning Subjects to Treatment Groups

The randomization schedule for treatment allocation was generated from a seed number and program written with SAS software. Treatments were randomly assigned to consecutive treatment numbers using a fixed block randomization scheme. Blocks we assigned to each of three age groups: 18-29, 30-45 and 45-65. Subjects were randomized within age groups to one of the two study treatments in a 1:1 ratio. Each subject received 6 weeks of treatment.

4.5 Efficacy and Safety Assessments

Treatment day procedures are presented in Table 1.

Table 1: Study Schematic

Study Procedures	Screening	Day 1 (Baseline)	Day 42 Week 6
Informed Consent	X		
Medical History/ Demographics	X		
Inclusion/Exclusion Criteria	X	X	
Mini-Mental State Examination	X		
Geriatric Depression Scale	X		
RAVLT Testing	X	X	X
CogScreen Testing	X	X	X
Dispense Product/Placebo		X	
Record Concomitant Meds	X	X	X
AE Assessment		X	X
Assess Compliance/Pill count			X

The efficacy measures for the study are described below:

Rey Auditory Verbal Learning Test (Strauss 2006)

The Rey Auditory Verbal Learning Test (RAVLT) is a standardized, widely used neuropsychological test of memory. The RAVLT is one of the most commonly used tests of memory in psychopharmacology research. The test was originally developed in the 1940s and has proven useful in evaluating verbal learning and memory, including proactive inhibition, retroactive inhibition, retention, encoding versus retrieval, and subjective organization. The standard RAVLT begins with a subject being read a list of 15 unrelated words at the rate of one word per second. The examiner then asks the subject to recall as many words as possible (RAVLT Trial 1; RAVLT1). This procedure is then repeated four more times with the same list of words (RAVLT Trials 2-5), these trials are referred to as “acquisition trials” and the number of correct responses is summed (RAVLT Sum 1-5). This score, RAVLT Sum 1-5, was chosen as the primary outcome measure for the current study. The rationale for selecting RAVLT Sum 1-5 was that this variable measures verbal learning or what is often referred to as “short term

memory." After the fifth trial the subject is read a second list of words (List B) referred to as an "interference list." The subject is then asked to recall as many words as possible from the original list. This is referred to as the "immediate" or "short delay" recall trial. After 30 minutes the subject is asked again to recall as many words as possible from the original list. This is referred to as the "long delay" recall trial. Retention is expressed as the percent of recall following the short and long delay compared to Trial 5.

CogScreen Test (Kay, 1995 & Crook, 2009)

CogScreen® is a standardized, validated computer-administered and scored neuropsychological test battery developed by Dr. Gary Kay and his colleagues. The battery was designed to rapidly assess deficits or changes in attention, immediate and working memory, visual perceptual functions, sequencing functions, logical problem solving, calculation skills, reaction time, simultaneous information processing abilities, and executive functions. Initially the test was designed to meet the U.S. Federal Aviation Administration's (FAA) need for an instrument that could detect subtle changes in cognitive functioning; changes which, left unnoticed, may result in poor pilot judgment or slow reaction time in critical operational situations.

In neuropsychological research CogScreen® has proven to be a highly sensitive test to the presence of mild brain dysfunction secondary to injury or disease and to changes in brain functioning caused by various medications, sleep deprivation, allergen exposure, hypoxia, and normal aging. The outstanding reliability and validity of CogScreen® is well documented in both the comprehensive test manual and in numerous publications.

Several versions of CogScreen have been developed for use in specific populations. One version of the battery, CogScreen®-Aeromedical Edition, is used worldwide in the medical evaluation of pilots with known or suspected neurological and/or psychiatric conditions. For example, the test is used by the FAA to monitor the neurocognitive functioning of HIV seropositive pilots. The battery is also used by major airlines around the world and by military organizations in selecting pilots and in conducting aeromedical research. CogScreen® is a proven predictor of flight performance for both student pilots and commercial aviators.

In addition to the Aeromedical Edition, other versions of CogScreen® have been used to detect the impact of medications on brain function and have provided the basis for regulatory agency approved drug claims such as "non-sedating" and "maintains focus". Among the pharmaceutical and nutraceutical agents investigated with CogScreen® are the following categories: antihistamines, stimulants (ADHD medications), atypical antipsychotics, antihypertensives, aspartame, cholinesterase inhibitors, statins, antibiotics, antimuscarinics, and hormone replacement therapies.

CogScreen Subtest Descriptions

Pathfinder Number

PF was adapted from the Trail Making Test, one of the most widely used tests of information processing, psychomotor speed and visual scanning ability (Strauss 2006). After viewing a

number or letter displayed in the center of the screen, the respondent's task is to select one of the four quadrants containing the next number in the sequence. Three of the four numbers are updated following each response. The performance measures include: (a) the median response time to complete each sequential step (PF Number Speed [PFNRTC]); (b) response accuracy (PF Number Accuracy [PFNACC]); (c) thruput (PF Number Thruput [PFNPUT]); and (d) a coordination measure indicating the respondent's proximity to the center of the target numbers and letters (PF Number Coordination [PFNCOOR]). PF measures number sequencing skills, motor coordination, and visual scanning.

Matching to Sample

MTS is a visuospatial working memory task. The examinee's task is to determine which of two 4x4 checkerboards matches a previously presented checkerboard. MTS provides measures of response speed (MTSRTC), response accuracy (MTSACC), and response efficiency (MTSPUT).

Symbol Digit Coding

SDC is a measure of information processing speed. The examinee's task is to pair digits to symbols using a key which displays the symbol-digit pairs during the 120 second trial. Upon completion of the 120 second trial there is a test of immediate and delayed recall that is a measure of memory. There are measures of speed (SDCRTC), efficiency (SDCPUT), accuracy (SDCACC), immediate recall (SDCIRACC) and delayed recall (SDCDRACC).

Visual Monitoring (Divided Attention Test Part I)

DAT is a measure of visual choice reaction time. During this 60-second task the examinee observes the movement of a cursor within a circle which is marked at the top and bottom by a second color. The examinee's task is to tap a response box whenever the cursor crosses into the area at the top or bottom of the circle. There are measures of response speed (DATIRTC) and impulsive responding (DATIPRE).

Previous Number (Dual Task Test Previous Number Alone)

DTTPNA is a measure of concentration or working memory. The examinee's task is to recall the number previously displayed in a box at the top of the screen. The number displayed is a 1, 2, or a 3. After the previously presented number is replaced by a 1, 2, or 3, the examinee responds to indicate which number was previously shown in the box. The test provides a measure of response accuracy (DTTPNACC).

Continuous Performance (KCPT)

KCPT is a continuous performance test, also known as the Kay Continuous Performance Test (KCPT). The KCPT is a measure of vigilance. The examinee's task is to respond as quickly as possible, by tapping the spacebar, whenever a specified symbol briefly appears. The specified symbol occurs at a low rate of item presentation. The subject must discriminate the specified symbol from other symbols and maintain their level of performance for a period of 12 minutes.

There are measures of total correct hits (HITS6), response speed (HITRT6), lapses (OMISS6), commissions (COMIS6), and perceptual sensitivity (DPRIME6).

5. STATISTICAL METHODS

The study was powered at 90% using sum of scores across the five acquisition trials on the RAVLT as the primary outcome measure (i.e. RAVLT Sum Trials 1-5).

The primary efficacy endpoint of the study is the sum of 5 acquisition trials on the Rey Auditory Verbal Learning Test (RAVLT Sum Trials 1-5) for the modified ITT population. The primary model for statistical analysis was a univariate Analysis of Covariance (ANCOVA). Treatment was added as a fixed effect. Treatment groups were first compared on age and education and were found to be comparable. Therefore, the single covariate for each comparison of outcome variables was the Baseline performance score. Missing data were not imputed.

In addition, performance on all other secondary endpoints (RAVLT and CogScreen variables) were analyzed using the same model.

6. STUDY POPULATION

Subject populations and disposition are shown in Table 2. A total of 96 subjects were enrolled and randomized to one of the two treatment groups.

Of the 96 subjects randomized, seven subjects were excluded from the efficacy (mITT) analysis. Three subjects were lost to follow-up (Subjects 027, 110, and 156) and four were noncompliant with study product (Subjects 056, 067, 113, and 119; these subjects took less than 80% of study product). All subjects (96) who were administered at least a single dose of study drug are included in the Safety Population.

Table 2: Subject Populations for Analysis

	Placebo (N=49)	VNF (N=47)	Overall (N=96)
Safety Population	49 (100.0%)	47 (100.0%)	96 (100.0%)
ITT Population	46 (93.9%)	45 (95.7%)	91 (94.8%)
mITT Population	46 (93.9%)	43 (91.5%)	89 (92.7%)

Safety Population = All randomized subjects who received any study medication.
ITT Population = All randomized subjects who received at least one dose of study drug and provided data at baseline and EOS.
mITT Population = All randomized subjects who were compliant with study drug (took ≥ 80% of study product) and provided data at baseline and EOS.

Demographic characteristics are presented in Table 3. The overall population (SAF) was 57.3% Female/42.7% Male and 76.0% White, with a mean age of 48.4 years. Screening characteristics were comparable for the two treatment groups.

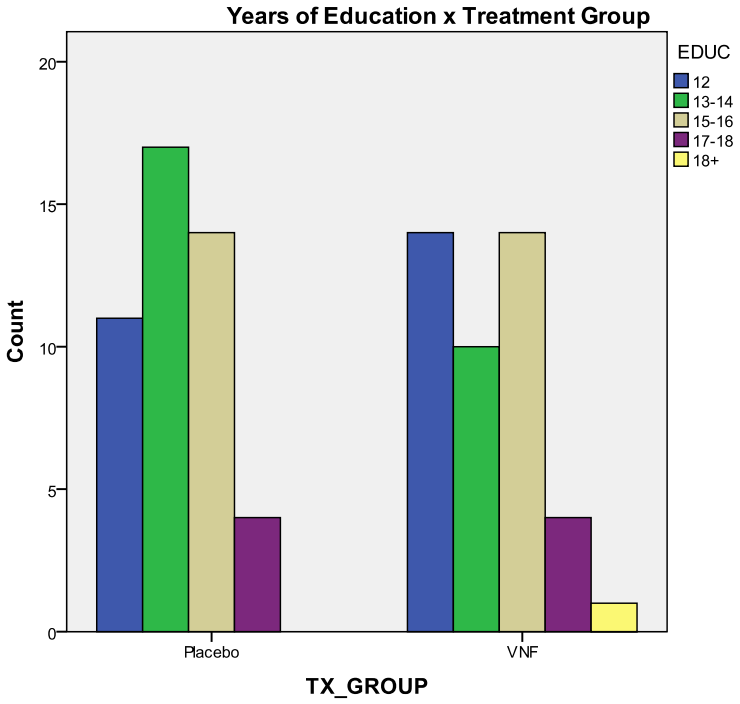
Table 3: Demography of the Safety Population

Characteristic	Placebo (N=49)	VNF (N=47)	Overall (N=96)
Age (years)			
Mean	48.41	48.43	48.42
Median	52	50	51
SD	11.74	11.03	11.34
Min, Max	19, 65	18, 64	18, 65
Gender			
Female	29 (59.2%)	26 (55.3%)	55 (57.3%)
Male	20 (40.8%)	21 (44.7%)	41 (42.7%)
Race			
White	39 (79.6%)	34 (72.3%)	73 (76.0%)
Black	4 (8.2%)	7 (14.9%)	11 (11.5%)
Hispanic	3 (6.1%)	4 (8.5%)	7 (7.3%)
Asian	1 (2.0%)	0 (0.0%)	1 (1.0%)
Other	2 (4.1%)	2 (4.3%)	4 (4.2%)
Years of Education			
12	12 (24.5%)	15 (31.9%)	27 (28.1%)
13 – 14	18 (36.7%)	11 (23.4%)	29 (30.2%)
15 – 16	15 (30.6%)	15 (31.9%)	30 (31.3%)
17 – 18	4 (8.2%)	4 (8.5%)	8 (8.3%)
More than 18	0 (0.0%)	2 (4.3%)	2 (2.1%)
Mini-Mental State Exam			
Mean	28.5	28.8	28.6
SD	1.28	1.10	1.20

For the efficacy analysis population (mITT), the mean age was 48.4 years. There was no difference between the subjects who received FOCUSfactor and those who received placebo with respect to age ($F = 0.015$; $df = 1$; $p = 0.90$).

Subjects in the two treatment groups (mITT) were also of comparable education (Chi Square = 3.08, $df = 4$; $p = 0.55$). The distribution of years of education for the two treatment groups is shown in Figure 1.

Figure 1: Education Demographics



7. EFFICACY RESULTS

7.1 Primary Endpoint: RAVLT Sum Recall Trials 1-5

Results for the primary endpoint, sum recall for the 5 RAVLT acquisition trials (RAVLT15), found that subjects who received 6 weeks of FOCUSfactor recalled significantly more words (Mean = 51.9) over the 5 acquisition trials compared to subjects who received placebo (Mean = 49.7) (Table 4). Comparing the results of the FOCUSfactor group to the placebo group shows a significant effect for Treatment (t = -2.98, df = 87, p = 0.002) (Table 5).

Table 4: Sum of Recall, RAVLT Trials 1-5 (RAVLT15 Week 6): Group Statistics

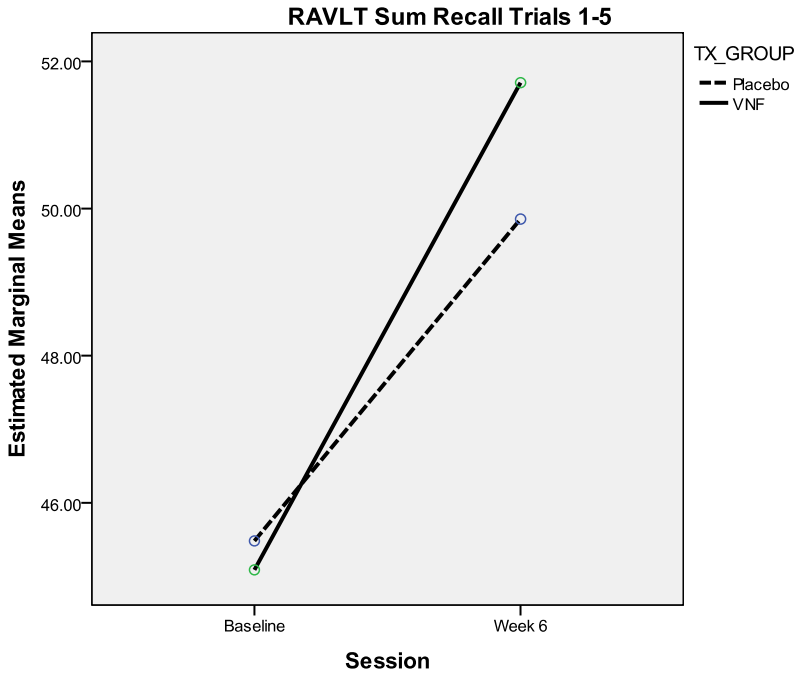
	Tx Group	N	Mean	Std. Deviation	Std. Error Mean
RAVLT15 Wk 6 corrected for Baseline	Placebo	46	49.6957	3.52986	.52045
	VNF	43	51.8837	3.37908	.51530

Table 5: Sum of Recall, RAVLT Trials 1-5 (RAVLT15 Week 6): Comparison of Means (T Test)

	t	df	p-value, 1-tailed	Mean Difference	Std. Error Difference
RAVLT15 Wk 6 corrected for Baseline	-2.983	87	.002	-2.18807	.73349

Total recall for Trials 1-5 for the Baseline and End of Study visit (Week 6) is shown in Figure 2.

Figure 2: Sum of Trial 1-5 RAVLT Recall at Baseline and End of Study (Week 6)



Covariates appearing in the model are evaluated at the following values: RAVLT5_2 = 11.03

Analysis of the change in recall from Baseline to Week 6 in the RAVLT Sum Trials 1-5 score (corrected for baseline score) shows that subjects who received FOCUSfactor had a mean increase in recall of 6.5 words compared to 4.5 words improvement for those who received placebo ($t = -4.32$, $df = 87$, $p < 0.001$).These results demonstrate a significant beneficial effect for FOCUSfactor compared to placebo on a measure of verbal learning and short term memory.

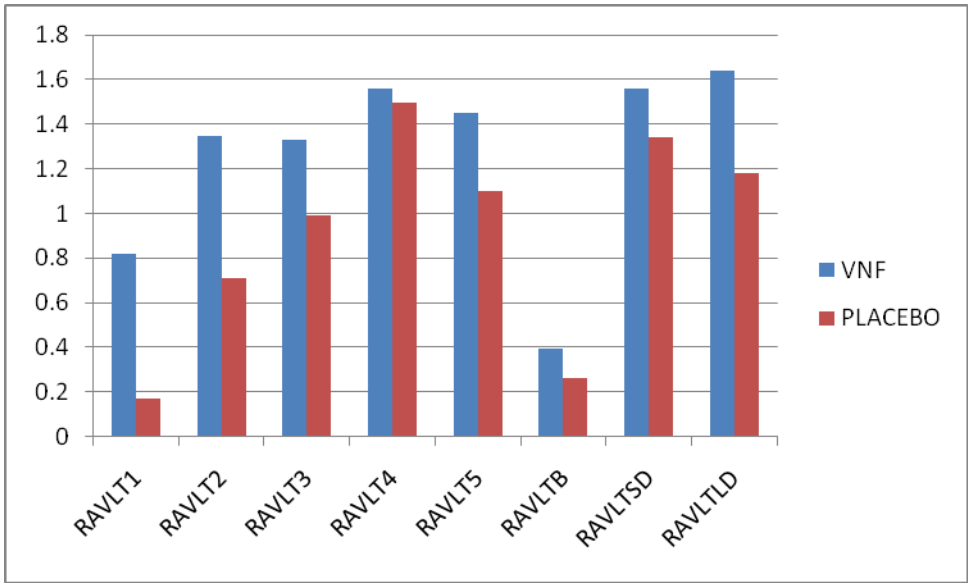
7.2 Secondary Endpoints: RAVLT

Analysis of individual acquisition trials reveals that the effect of FOCUSfactor on recall performance was most evident for Trial 1. The change in Baseline to Week 6 in recall for Trial 1 of the RAVLT was significantly greater for subjects who received FOCUSfactor than for those who received placebo ($t = -4.387$, $df = 87$, $p < 0.001$) (Table 6). The change in recall from Baseline to Week 6 for each of the RAVLT recall trials is shown in Figure 3.

Table 6. Change from Baseline to Week 6; RAVLT Trial 1: Comparison of Means (T Test)

	T	df	p-value, 1-tailed	Mean Difference	Std. Error Difference
RAVLT Trial 1; Change from Baseline to Week 6	-4.387	87	<0.001	-1.00000	.22794

Figure 3. Change from Baseline to Week 6 for each RAVLT Recall Trial



Results for Trial 2 show a similar trend for greater improvement in the change from Baseline to Week 6 recall score ($t = -1.26$, $df = 87$, $p = 0.11$). Comparison of Week 6 RAVLT2 scores for the two treatment groups does reveal that subjects receiving FOCUSfactor recalled more words on Trial 2 (9.6 ± 1.7) than those receiving placebo (8.9 ± 1.8). This difference also approached significance ($p = 0.069$).

7.3 Secondary Endpoints: CogScreen

Secondary measures obtained from CogScreen support the findings obtained from the RAVLT. On measures of response accuracy it was found that subjects receiving FOCUSfactor were more accurate on a measure of working memory than subjects receiving placebo (DTTPAACC; $t = 1.89$, $df = 87$; $p = 0.031$). However, CogScreen showed no significant difference between the two treatment groups on measures of simple reaction time, delayed recall, impulsivity, or vigilance.

Analysis of the correlations between CogScreen and RAVLT scores indicates that recall on RAVLT Trials 1 and 2 is most related to performance on CogScreen measures of working memory (DTT Previous Number and Symbol Digit Coding). For RAVLT Trial 1 these two

CogScreen scores (Previous Number Alone and Symbol Digit Coding) accounted for 16.7% of score variance (R = 0.41).

8. SAFETY RESULTS

8.1 Adverse Events

Treatment emergent adverse experiences (AEs) were coded by MedDRA®. Adverse events occurring in > 2% of patients are presented in Table 7. The majority of AEs were mild or moderate in intensity. A greater percentage of subjects receiving placebo than FOCUSfactor experienced AEs.

Table 7: Summary of Treatment Emergent Adverse Events > 2%

AE TERM	Placebo (N=49)	VNF (N=47)	Overall (N=96)
Number of Subjects Reporting an AE	21 (42.9%)	16 (34.0%)	37 (38.5%)
Number of AE Reported	33	26	59
Headache	4 (8.2%)	7 (14.9%)	11 (11.5%)
Nausea	4 (8.2%)	2 (4.3%)	6 (6.3%)
Constipation	4 (8.2%)	1 (2.1%)	5 (5.2%)
Insomnia	3 (6.1%)	1 (2.1%)	4 (4.2%)
Bloated	2 (4.1%)	0 (0.0%)	2 (2.1%)
Cramps	1 (2.0%)	1 (2.1%)	2 (2.1%)
Diarrhea	1 (2.0%)	1 (2.1%)	2 (2.1%)
Bronchitis	1 (2.0%)	1 (2.1%)	2 (2.1%)
Indigestion	1 (2.0%)	1 (2.1%)	2 (2.1%)

Headache was the most commonly reported adverse event and was noted more frequently in subjects receiving FOCUSfactor treatment (14.9%) versus placebo treatment (8.2%). When evaluated by body system, gastrointestinal disorders were the most commonly reported adverse events and the incidence of these events, such as nausea and constipation, were higher in placebo treated subjects. None of the AEs were serious.

8.2 Concomitant Medications

Concomitant medications initiated during the double-blind treatment period and occurring in > 2% of patients are presented in Table 8. A greater percentage of subjects in the placebo treatment group received concomitant medications during the trial.

Table 8: Summary of Treatment Emergent Concomitant Medications >2%

Concomitant Medication	Placebo (N=49)	VNF (N=47)	Overall (N=96)
Number of Subjects Receiving a Concomitant Medication	12 (24.5%)	10 (21.3%)	22 (22.9%)
Number of Concomitant Medication Taken	19	11	30
Ibuprofen	4 (8.2%)	2 (4.3%)	6 (6.3%)
Multivitamin	1 (2.0%)	1 (2.1%)	2 (2.1%)
Albuterol	2 (4.1%)	0 (0.0%)	2 (2.1%)

9. CONCLUSION

The present study shows that FOCUSfactor improves memory, concentration and attention (e.g., focus) in healthy adults following six weeks of administration. The effect is particularly pronounced in "working memory." The improvement in memory seen in this study for individuals who received FOCUSfactor is comparable to a decrease of 20 years in cognitive aging. In addition, FOCUSfactor was found to be very well tolerated.

10. COGNITIVE RESEARCH CORPORATION

The study was conducted by Cognitive Research Corporation (CRC), a privately-held, full-service contract research organization (CRO) known for expertise in evaluating the effects of medications, nutritional supplements, and foods on mental functioning and sleep. CRC offers a full range of services for Early Drug Development; Product Registration; and Scientific/Medical Affairs, including Phase IV/ post-marketing research. CRC's extensive network of clinical investigators are trained to support cognitive and other studies utilizing state-of-the-art computer-based cognitive testing and driving simulators. CRC provides clinical development services for pharmaceutical, nutraceutical, biotechnology, and medical device companies as well as commercial airlines, United States and international military organizations, and major international shipping corporations. With decades of experience in conducting clinical trials, including projects for two of the top three largest international pharmaceutical companies, CRC has a proven track record in assessing both the efficacy and safety of products across a wide range of indications.

CRC offers a broad range of proprietary technologies, including sophisticated neuropsychological assessment and state-of-the-art technologies to assess cognition, mood, and perceptual-motor functioning. The CogScreen® battery which is used worldwide by airlines and military aviation organizations in pilot evaluation and selection, provides sensitive and reliable measure of attention, information processing speed, working memory, visual perceptual functioning, multitasking ability, and executive function. Results from studies employing CRC's

psychometric methodologies (CogScreen® and Psychologix®) have served as the basis for establishing drug claims such as "non-sedating" and "maintains focus" and the only Qualified Health Claim related to cognition, mood or behavior approved by the U.S. Food and Drug Administration (FDA) for a nutraceutical product.

Dr. Gary Kay, President, is a clinical neuropsychologist and Associate Professor of Neurology at Georgetown University. Dr. Kay has been involved in research, teaching and clinical service for nearly three decades. He specializes in the assessment of neurocognitive function and is the developer and publisher of CogScreen®. Dr. Kay has served as the principal investigator on more than 20 CNS-based studies, has written more than 75 CNS publications and delivered hundreds of invited lectures worldwide.

Dr. Thomas Hochadel, Chief Operating Officer, has over 20 years of experience in planning, managing and conducting clinical research trials, with an emphasis on cognition and CNS disorders. Dr. Hochadel's experience includes Phase I-IV clinical trials involving a wide variety of subjects, including healthy volunteers, elderly volunteers, individuals with age-associated memory impairment, and patients, including those with Alzheimer's disease, ADHD, bipolar, depression, Parkinson's disease, schizophrenia, and sleep disorders. Prior to joining CRC, Dr. Hochadel conducted CNS research programs at Scirex, Covance and Somerset Pharmaceuticals.

Additional information about Cognitive Research Corporation can be found by visiting the company's website at www.cogres.com.