

Ageless™ Clinical Trial Summary

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I. Background:

The emerging scientific discipline known as anti-aging has focused primarily on the protection and repair of the body. New technologies on the horizon include stem cells, gene therapies, nanotechnology and a variety of natural products and pharmaceuticals for maintaining anabolic drive, immunity and cardiovascular health. Studies show, however, that 40% of those reaching age 85 will suffer from significant brain degeneration or senility. It is imperative, therefore, that more attention and research be directed towards protecting and maintaining optimal brain function.

One of the most important advances in this arena was the research of James Joseph and colleagues, published in the Journal of Neuroscience in 1998.¹ These scientists demonstrated that oxidative stress is a major factor in age-related neurodegenerative disease, and showed in a rat model that many of its deleterious effects could be retarded or even reversed by feeding concentrates of anthocyanin-rich fruits, primarily blueberries. The proposed mechanisms of action included effective quenching of free radicals, improved membrane fluidity and the ultimate restoration of youthful balance, coordination, memory and learning capacity. Importantly, feeding blueberry concentrate spared vitamin E, so that vitamin E levels in the brain were higher than control animals. This is a significant finding, as increased vitamin E has been associated with decreased risk for Alzheimers disease.²

The development of MetaBerry was based on the above research, including anthocyanin-rich concentrates of blueberry, cranberry, black cherry and concord grape. 20 mg of alpha lipoic acid and 20 mg of a standardized concentrate of ginkgo biloba were added per one-ounce serving and the mixture is delivered in a liquid aloe concentrate. The ORAC (the recognized test for anti-oxidant potency) score as determined by independent laboratory testing is 3,129 ORAC units per fluid ounce. Keep in mind that the ORAC value of the average American's total dietary intake is 1,200 to 1,500 per day.

II. The Current Work

Beyond the protective and potentially restorative effects of anthocyanin-rich fruits and vegetables, a growing body of research is demonstrating potential benefits from anti-inflammatory agents, stress management, additional free radical quenchers and nutrients such as niacin and vitamin B-6 that play critical roles in brain function.

Brain Busters:

1. Stress
2. Free radicals
3. Sub-optimal Vitamin B-3
4. Sub-optimal B-6
5. inflammation

Brain Boosters provided by Ageless:

- theanine, Serenix™, Siberian ginseng, Pyridoxal-5-phosphate
- green tea polyphenols, Pyridoxal-5-phosphate (P5P)
- Niacin, niacinamide
- Pyridoxal-5-phosphate
- Protectin™, green tea polyphenols

III. Measuring Brain Function

Until recently, the only reliable assessment tools for measuring brain function were EEG and a variety of functional tests for dementia (eg. MMSE and ADAS-Cog). Unfortunately, these tests were relatively ineffective for identifying early degeneration, and EEG could only be performed

in a clinical setting.

The recent breakthrough in testing mood, memory and cognition came from technology capable of measuring reaction time in milliseconds. Virtually all recently manufactured computers have this capability. The only remaining hurdle was to develop software to effectively utilize this capability and a central database to compare results to others of the same age and gender. This was accomplished by Cognitive Care, Inc. 2102 Business Center Drive, Suite 130, Irvine, CA 92612.

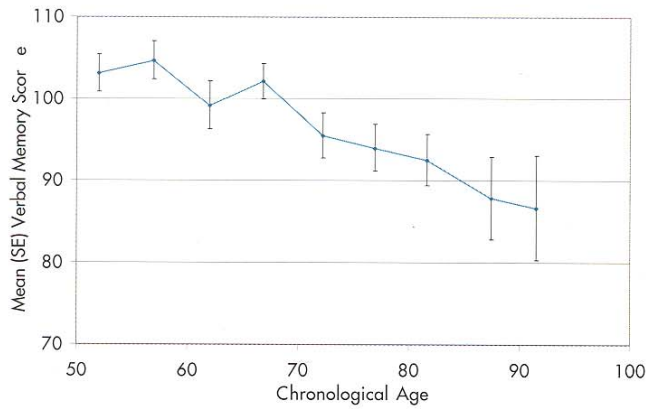
The Cognitive Care system is based on neurocognitive, chronometric assessment technology (NCAT), a proprietary internet-based assessment tool that measures mental and physical reaction time. NCAT includes computerized cognitive tasks to assess the brain's information-processing (speed and accuracy) across several domains (memory, attention, reasoning).

This combination of tests utilizing on-line brain processing speed technology has been validated at four major universities and provides instantaneous comparison to an enormous national database. In a test measuring my information processing speed, the Cognitive Care results differed from a 12-sensor EEG by only two milliseconds.

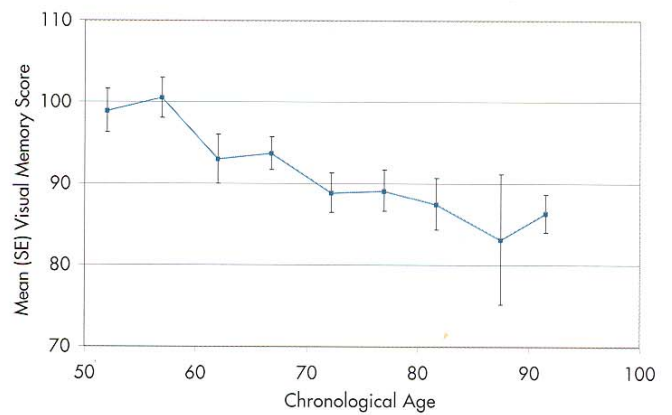
IV. The Bad News:

Results presented at the annual conference of the EEG and Clinical Neuroscience Society (ECNS) in September 2002 paint a clear picture of what "normal" brain aging looks like.

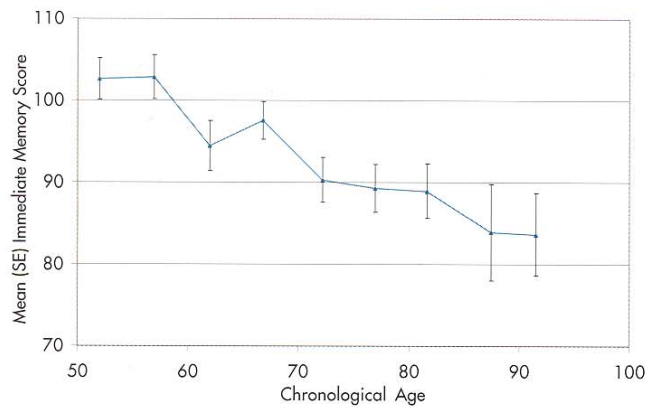
A. Verbal Memory vs Age



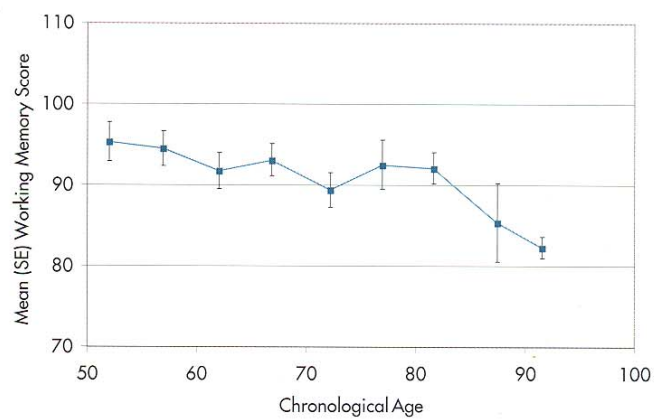
B. Visual Memory vs Age



C. Immediate Memory vs Age

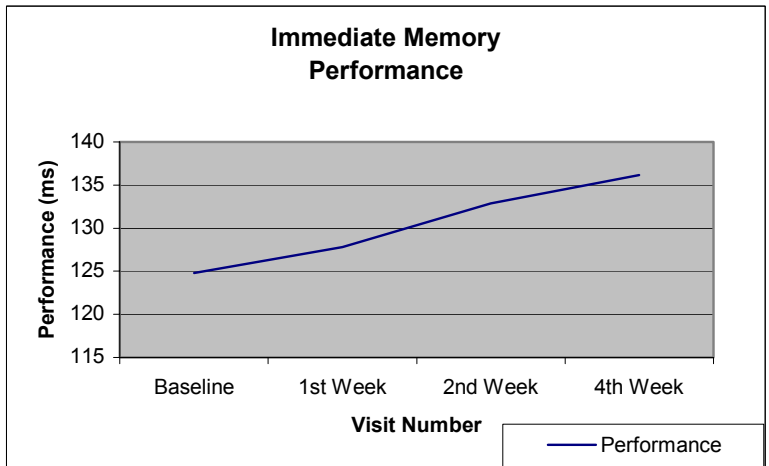
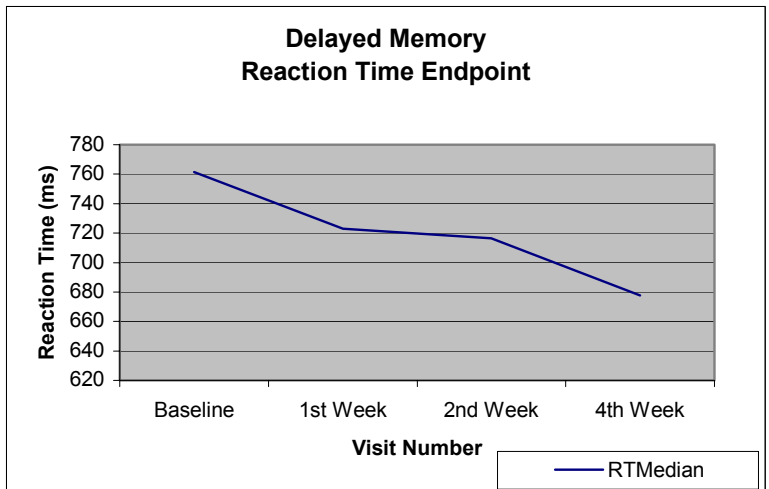
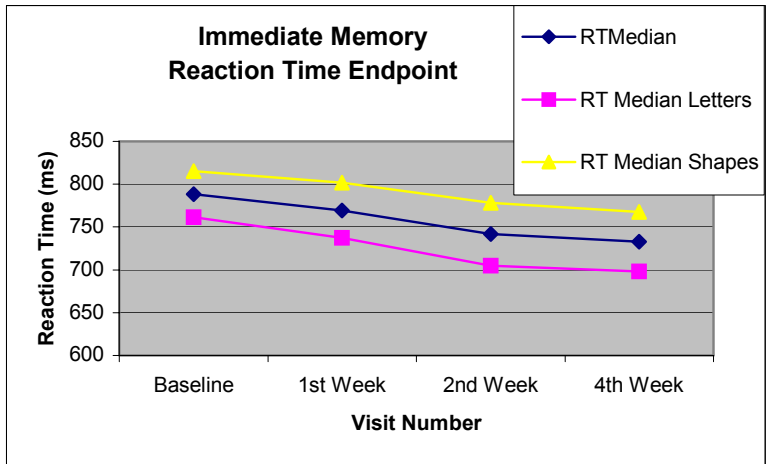


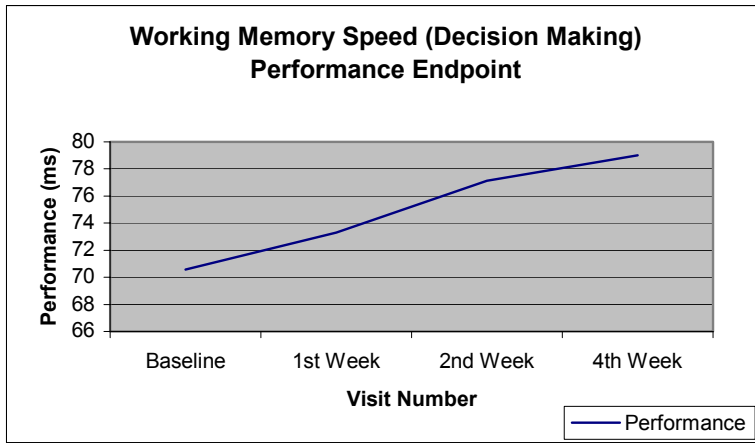
D. Working Memory vs Age



V. The Good News

Now look at the results of a trial conducted by Cognitive Care with individuals taking Ageless. Please remember that this is literally cutting-edge technology. This data was obtained in a clinical setting, not under rigidly controlled conditions, and must therefore be regarded as preliminary and experimental. Nevertheless, the results experienced by this test group were so remarkable, we moved immediately to conduct controlled trials over a longer period of time with 120 participants (in progress).

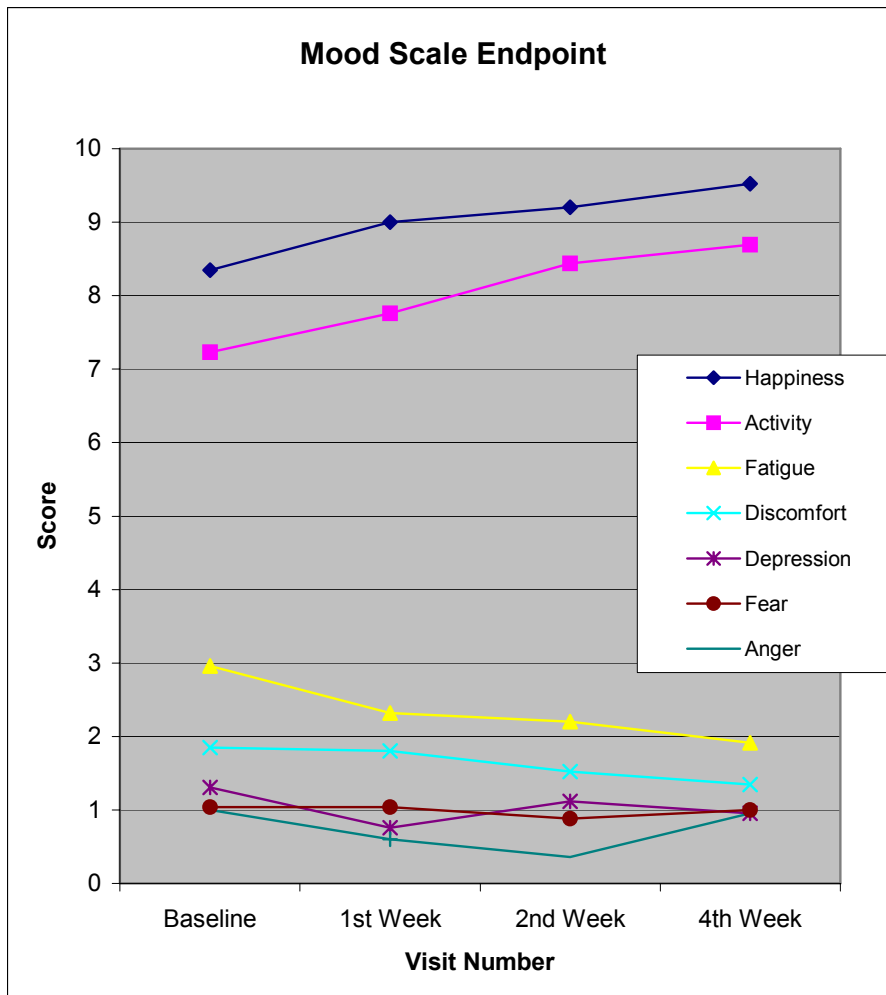




VI. Mood

The tag line for the Ageless product is:
“Age is a feeling, not a number.”

And while this makes sense to anyone who has thought about the aging process, it is important to define as much as possible what those feelings might be. We used another Cognitive Care program, the same one used by NASA, to measure indicators of happiness, activity, fatigue, discomfort, depression fear and anger.

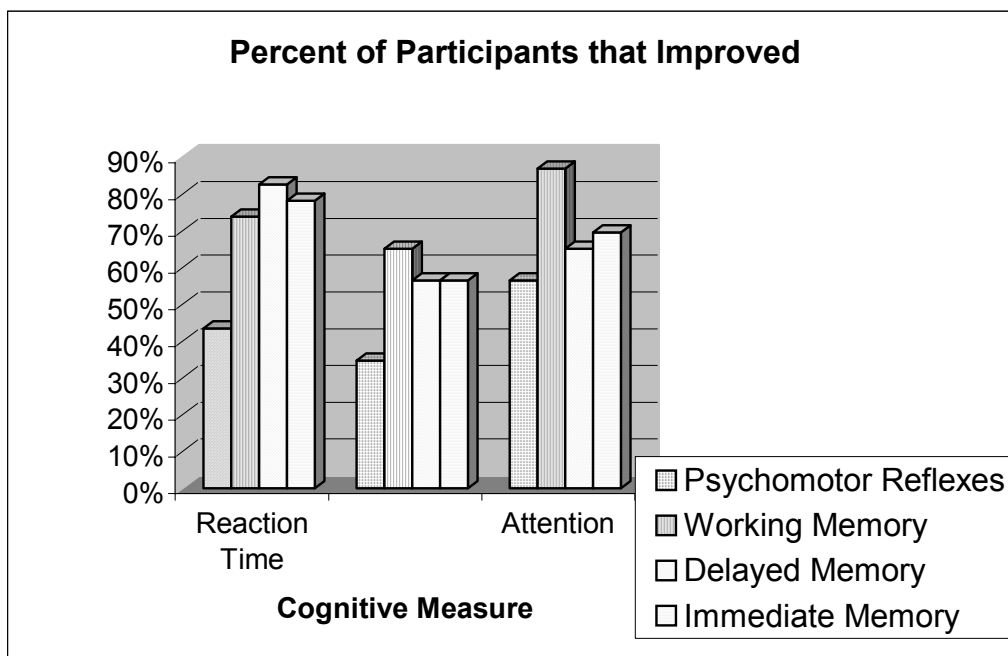


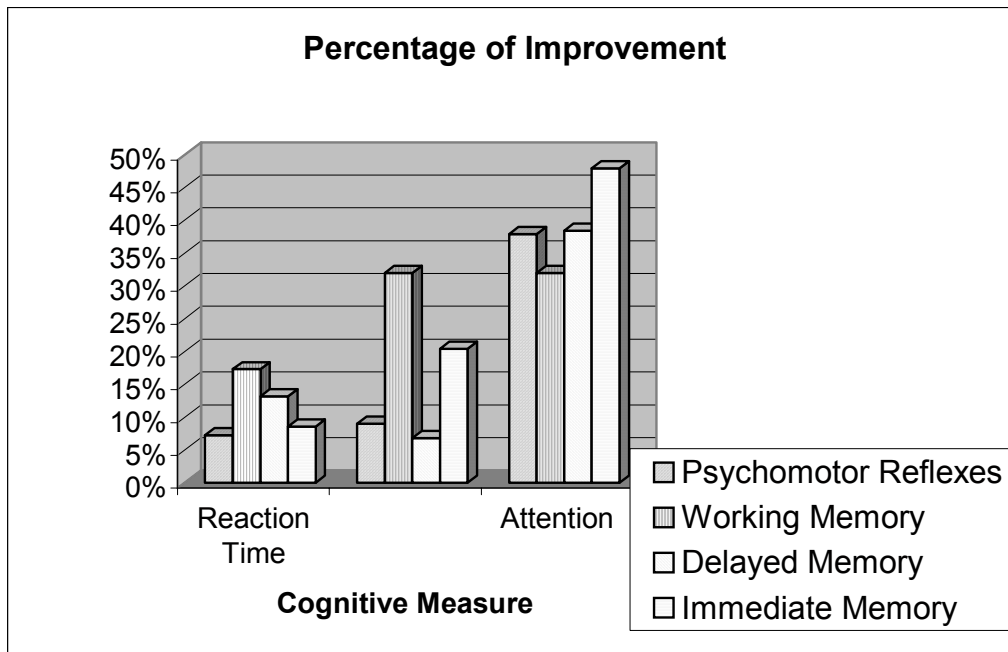
VII. Statistics

Unfortunately, even when statements are backed up with "facts and figures," you must be skeptical. Statistics must be evaluated just like any statement, because they are, after all, simply numerical claims subject to misinterpretation and manipulation.

Regarding changes reported for a group of subjects, it is useful to know the mean or average improvement, but this must be accompanied by information on the distribution of these changes and the degree of change. If the average improvement for the group was due to a remarkable improvement in one subject and only modest or no improvement in the others, the results would be essentially meaningless.

To address this, we looked at the number of people who improved in each of the above categories, and then looked to see if the improvement was significant.





Notice that the percent of participants who improved was generally extremely high, in the 60 to 80% range; and that the degree of change was also impressive. What if you could improve your working memory by 32% or your attention (ability to concentrate) by 38% in four weeks? Again, we are not claiming that these results will be obtained by everyone, or that they represent average results for a large population. But the subjects for this study were randomly selected by Cognitive Care from respondents to a newspaper ad. They represent, to the best of our ability, average Americans with an average diet, experiencing the kinds of stress that you and I face.

VIII. Ingredient Summary

Serenix™:

Proprietary extract from *Zea mays* (corn leaf).

Serenix™ is a unique extract from corn leaf that helps support healthy mood, positive outlook, and helps maintain normal sexual response and desire.

Energetix™:

Energetix™ is the patented name for the proprietary 3-ginseng blend that is unique to Ageless. Energetix contains:

- A. Standardized, Econet-derived Panax ginseng specially processed to a highly potent extract [trade named Heavenly Ginseng™]
- B. Rhodiola extract from Unigen Pharmaceuticals (a.k.a. Ultrin TG or Tibetan ginseng)
- C. Siberian ginseng (*Eleutherococcus senticosus*).

Both Heavenly Ginseng and Ultrin TG were studied in an animal model measuring stamina and energy. Both showed a 200% improvement after just 4 days of supplementation, with no increase in resting cortisol levels. This strongly suggests that the bioenergetic improvement is not derived from increased stress (such as experienced with caffeine and ephedrine) but rather an improvement in cellular energy efficiency.

Protectin™

Protectin is the Oasis tradename for the patented botanical complex known as Univestin, developed by the Oasis research partner, Unigen Pharmaceuticals, Inc. Protectin has been shown, in genomic, biochemical and biological studies, in both animals and humans, in vitro and in vivo, to have a remarkable ability to reduce the discomforts associated with the aging process. Licensed health care professionals can access clinical and laboratory data on this

compound at OasisDr.com.

A 90-day randomized, multi-center, double-blind, placebo-controlled human trial on Protectin was carried out by a prestigious research organization in Montreal. Physical function and range of motion was measured by a validated research protocol (WOMAC). At 30 days, Protectin produced statistically significant improvements compared to placebo.

Ornithine alpha ketoglutarate (OKG)

Ornithine alpha-ketoglutarate (OKG) is a salt formed of two molecules of ornithine and one molecule of alpha-ketoglutarate. It possesses significant anabolic and bioenergetic activity in human metabolism, and may play a critical role in cellular detoxification and antioxidant defense.^{3,4} Alpha ketoglutarate is a vital component of Krebs and glucose-alanine cycles. During exercise, there is evidence that this essential nutrient is a rate limiting factor contributing to fatigue. Mobilization of branched chain amino acids depends upon adequate levels of alpha ketoglutarate and clinical trials with oral supplementation have resulted in enhanced human performance.⁵

Pyridoxal-5-phosphate (P-5-P)

Pyridoxal-5-phosphate is the activated coenzyme form of vitamin B6, and is necessary for myriad biochemical functions including amino acid absorption and metabolism, energy production, immunity and brain function. This coenzyme form is easier to absorb, and has been the subject of more than 5000 metabolic studies. Importantly, sub-optimal vitamin B-6 intake is quite common in the U.S. and a deficiency of this critical nutrient has been associated with increased psychological stress, impaired energy metabolism, brain degeneration and increased risk to cardiovascular disease.^{6,7} Recently, studies have also show that vitamin B-6 may play an important role in the activation of critical antioxidant defenses.^{8,9,10}

Niacin / niacinamide

Vitamin B3 is necessary for thousands of biochemical reactions in the body, and is necessary for cell respiration and the release of energy from carbohydrates, fats and proteins. In addition, these forms of vitamin B3 support mental function, including memory.¹¹ A 6-year evaluation of cognitive function with healthy elderly subjects age 66 to 90 demonstrated a significant association between niacin levels and certain brain functions related to learning.¹²

Green Tea Extract

Traditional Chinese Medicine has espoused the use of green tea for centuries, and its beneficial effects have been shown in more than 1,156 Medline studies. Green tea contains antioxidant compounds known as polyphenols, which appear to help protect brain function.^{13,14} In vitro studies have also identified valuable anti-inflammatory effects of green tea polyphenols.¹⁵

Green tea also contains theanine, an amino acid that has been shown to promote relaxation without drowsiness. Animal and human studies suggest that theanine may provide additional protection for brain function.^{16,17}

IX. Conclusion

Data from this study was evaluated by biostatisticians from the University of California, Irvine. Their interim report includes the following statement:

Immediate Memory is similar to the classic Sternberg task where a string of stimulus "target" items to be remembered are followed by a "probe" item. The subject must decide yes or no if the probe item was a member of the previous target list. List length can be varied to provide an estimate of the short-term memory capacity of the individual. Both letters and spatial position are examined in this task. In terms of the

performance index there was a significant change across weeks of testing ($F(2,38) = 6.801, p = .003$), most noticeable comparing baseline to week 2. In addition, there was a significant improvement in the reaction time mean ($F(2,38) = 5.96, p = .0056$) and the standard deviation across the weeks of testing ($F(2,38) = 3.605, p = .0368$), again with the most noticeable improvements between baseline and week 2.

Overall the test for immediate memory showed the most robust changes across the weeks of testing, indicating improved immediate memory capacity, faster reaction time, improved sustained attention and more accurate processing of the information.

We are excited about this preliminary report because information processing speed has recently been found to be a reliable biomarker of aging and perhaps the best early indicator of brain degeneration.¹⁸

We believe that these preliminary results will be validated in more extensive trials and moreover, that consumers will experience significant improvements in mind, mood and energy for themselves. Oasis LifeSciences has partnered with Cognitive Care, Inc. to produce an internet-based version of the same test referenced above. This new Ageless Test will be available to associates with premier web sites.

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