
A Clinical Study on the Effects of a Dietary Supplement on Brain Health and Memory

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OBJECTIVE

The primary objective of this clinical study was to assess the efficacy and safety of a dietary supplement designed to affect different biomarkers of memory.

BACKGROUND

Memory is a critical function of the brain. It includes the ability to obtain, store, and process information, which is critical for learning and survival¹. Aging is the biggest known risk factor for memory decline, although some other types of physiological changes can also impact memory.

Memory decline can impact everyday activities and overall quality of life, so strategies to support memory are critical. Behavioral and lifestyle changes to support memory include not smoking, being physically active, reducing alcohol consumption, eating a Mediterranean-like diet rich in antioxidant compounds, and engaging in cognitive activities (among others)².

Some antioxidant compounds that may have a protective effect on the brain include astaxanthin, grapes, and vitamin E. Astaxanthin is a carotenoid antioxidant that can cross the blood brain barrier and has been studied for its positive effects on parameters of memory³⁻⁴. Grapes, grape juice, and grape extracts are sources of flavonoid antioxidants like proanthocyanidins that have been shown to have strong antioxidant activity. Grape extracts have been studied and demonstrated to have positive effects on learning⁵. Vitamin E is an essential fat-soluble antioxidant nutrient that is linked with cognitive performance⁶. Therefore, it was hypothesized that the combination of these three ingredients in a dietary supplement would improve and support various parameters of cognitive health, including memory.

STUDY DESIGN

One hundred healthy subjects (ages 40–70) with self-reported memory concerns were recruited for this 12-week, double-blind, placebo-controlled study. The subjects were randomly assigned to a memory supplement group (n=50) or a placebo group (n=50). Each group was instructed to take the memory supplement (9 mg astaxanthin, 250 mg grape extract, and 12 mg d-alpha tocopherol in two softgels) or placebo once daily with food for 12 weeks.

Subjects completed a series of cognitive tests administered at baseline and after 12 weeks. These tests assessed a wide range of cognitive abilities related to learning, attention, and memory. Subjects also completed additional computerized cognitive tests and a self-reported Everyday Memory Questionnaire-Revised (EMQ) at baseline and weeks 4, 8, and 12. The questionnaire asked a series of questions about common aspects of memory decline in everyday life.

Blood was collected at baseline and 12 weeks to measure parameters for liver and kidney function, circulating levels of Brain Derived Neurotrophic Factor (BDNF), and Malondialdehyde (MDA). BDNF plays a role in learning and memory, and MDA is a marker of systemic oxidative stress.

Subjects were also scanned using a Pharmanex BioPhotonic Scanner to measure their Skin Carotenoid Score at baseline and 12 weeks.

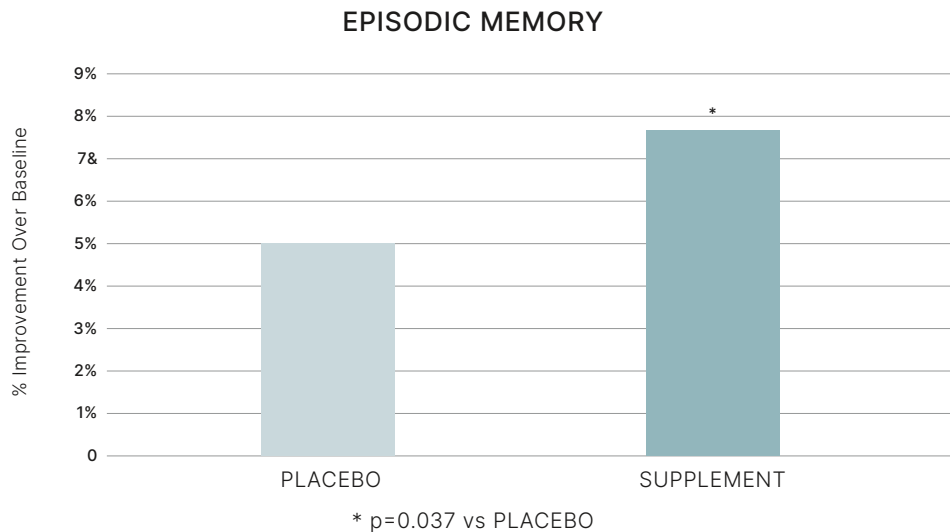
Finally, subjects had their weight and blood pressure measured at baseline and week 12.

RESULTS

EPISODIC MEMORY

Episodic memory is a cognitive process involving the retention, recall, and encoding of information about events and experiences⁷. In this study, episodic memory was assessed through the administration of several cognitive tests: numeric working memory (requiring subjects to remember a series of numbers displayed on a screen), location learning recall (requiring subjects to remember where pictures of objects were located on a 5×5 grid), and RAVLT delayed recall (requiring subjects to remember a list of words read aloud to them).

Based on the results of these cognitive tests, daily use of the supplement was associated with significantly greater improvements in episodic memory compared to the placebo group ($p=0.037$). The supplement group experienced a statistically significant 7.72% improvement in episodic memory from baseline to week 12, compared to a 4.98% improvement in the placebo group.



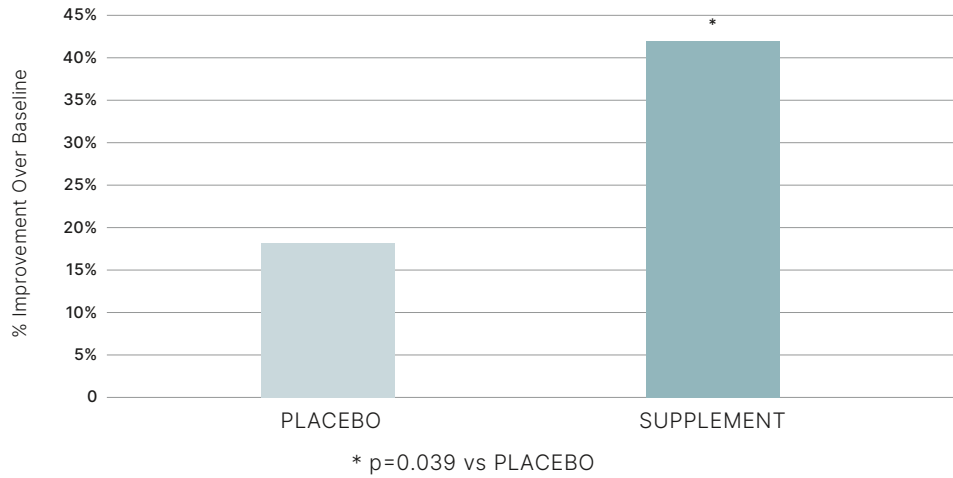
EVERYDAY MEMORY QUESTIONNAIRE

In this part of the study, participants were asked a series of 13 questions regarding memory issues. These questions assess the frequency of everyday experiences that indicate memory issues, such as:

- Forgetting when it was that something happened.
- Forgetting that you were told something yesterday or a few days ago.
- Forgetting to do things you said you would do and things you planned to do.
- Forgetting where things are normally kept or looking for them in the wrong place.
- Forgetting what you have just said while talking to someone.
- Forgetting to tell somebody something important or pass on a message.

The purpose of the Everyday Memory Questionnaire is to assess memory status in day-to-day life. The results demonstrated a statistically significant 42.08% improvement in self-reported everyday memory in the supplement group compared to an 18.09% improvement in the placebo group ($p=0.039$), indicating a subjective improvement in everyday memory in the supplement group.

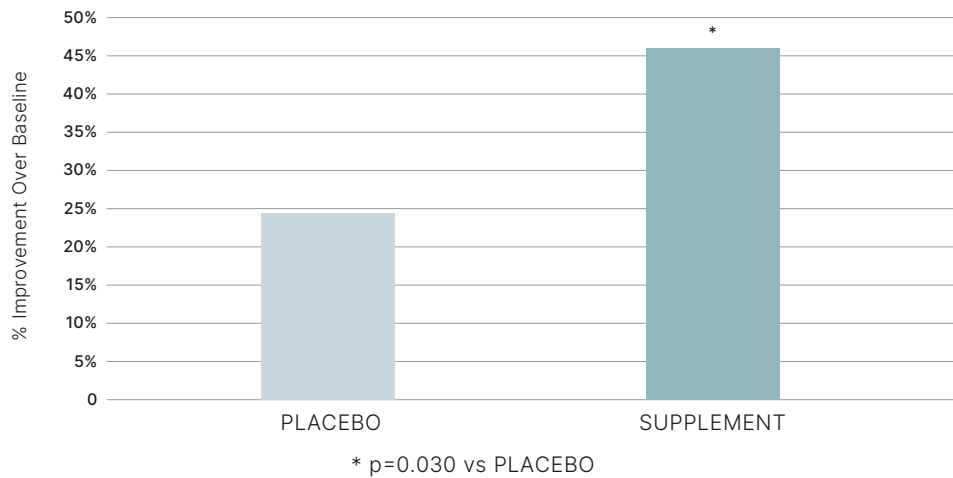
EVERYDAY MEMORY QUESTIONNAIRE



BRAIN DERIVED NEUROTROPHIC FACTOR (BDNF)

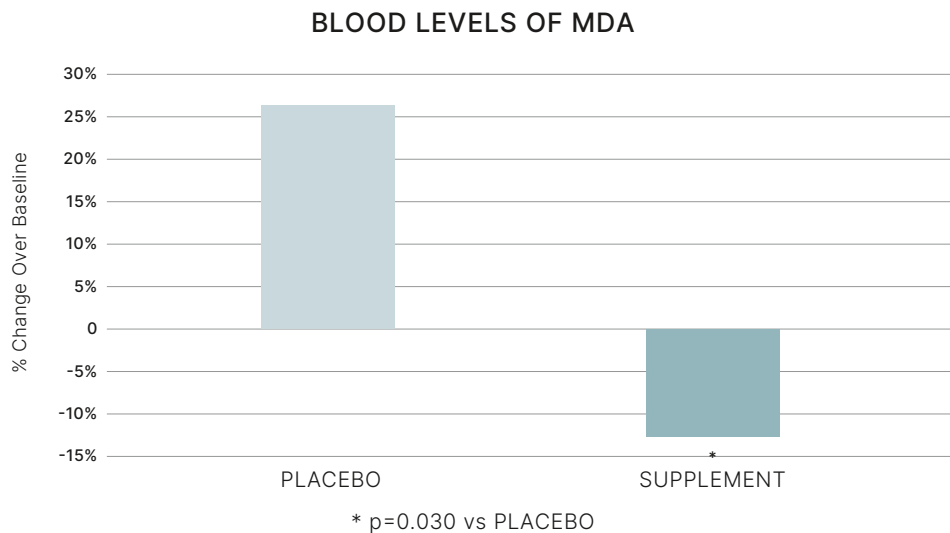
Brain Derived Neurotrophic Factor, or BDNF, is a protein that is involved in learning and memory. BDNF was measured in blood samples from all subjects at baseline and week 12. There was a statistically significant 46.10% increase in blood levels of BDNF in the supplement group, compared to a 24.41% increase in the placebo group (p=0.030).

BLOOD LEVELS OF BDNF



MALONDIALDEHYDE (MDA)

Malondialdehyde, or MDA, is a byproduct of cellular lipid peroxidation of polyunsaturated fatty acids and is often used as a biomarker of oxidative stress. MDA was measured in blood samples from all subjects at baseline and week 12. There was a statistically significant decrease of MDA (-12.49%) in the supplement group, compared to a 26.52% increase in the placebo group (p=0.040).



SKIN CAROTENOID SCORE

Subjects were scanned with the BioPhotonic Scanner S3 at baseline and week 12. The supplement group had a statistically significant increase in skin carotenoid score after 12 weeks, whereas the placebo group experienced no meaningful change in skin carotenoid score (p=0.006 vs placebo). The increase in skin carotenoid score is attributable to the astaxanthin found in the supplement formula.

SAFETY AND TOLERABILITY

There were no clinically significant changes between supplement and placebo groups for measurements of weight, blood pressure, or blood markers for liver or kidney function. No serious adverse events were reported in either group.

CONCLUSIONS

In this double-blind, randomized, placebo-controlled study, the addition of a nutritional supplement was shown to be effective in improving several parameters tested, including episodic memory, everyday memory, BDNF and MDA blood levels, and skin carotenoid scores.

Consuming the supplement led to significantly greater improvements in episodic memory compared to the placebo group after 12 weeks, as measured by the combination of several cognitive tests. Changes in episodic memory are one of the earliest signs of mild cognitive impairment⁷; so finding a statistically significant improvement in this parameter is very promising. Additionally, based on the Everyday Memory Questionnaire, participants in the supplement group reported significantly larger improvements in everyday memory compared to the placebo group, indicating the memory benefits manifest in common, everyday scenarios as well.

Blood testing confirmed a significant increase in BDNF in the supplement group. The increase in BDNF suggests that the memory blend may have a neuroprotective effect, possibly through its ability to increase this important compound. BDNF is critical for neuronal survival and growth, as well as synaptic plasticity.

Additionally, blood testing confirmed a significant decrease in MDA in the supplement group, indicating decreased systemic oxidative stress. Since oxidative stress is believed to be associated with worsened cognitive performance⁸, it is plausible that this decrease is another indicator that the memory blend may have neuroprotective benefits, possibly via its antioxidant activity. The significant improvement in skin carotenoid score in the supplement group also supports the antioxidant effects of the memory blend, since skin carotenoid score is an indicator of overall antioxidant status⁹.

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