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File: ■ Bacopa (Bacopa monnieri)
■ Microalgae (Haematococcus pluvialis)
■ Cognition
■ Illumina®

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RE: Bacopa Combination Supplement Improves Cognition and Memory in Patients with Mild Cognitive Impairment

Zanotta D, Puricelli S, Bonoldi G. Cognitive effects of a dietary supplement made from extract of *Bacopa monnieri*, astaxanthin, phosphatidylserine, and vitamin E in subjects with mild cognitive impairment: a noncomparative, exploratory clinical study. *Neuropsychiatr Dis Treat*. 2014;10:225-230.

Mild cognitive impairment (MCI) is more severe than age-related cognitive decline, but not as severe as a diagnosis of senile dementia or Alzheimer's disease. Early treatment of MCI may delay more severe decline. The purpose of this prospective, noncomparative, multicenter study was to evaluate Illumina® (Cristalfarma srl; Milan, Italy) for improving cognition in patients with MCI.

The 4 main ingredients of Illumina are bacopa (*Bacopa monnieri*), astaxanthin from *Haematococcus pluvialis* algae, phosphatidylserine, and vitamin E. The scientific rationale for the Illumina formulation may be briefly summarized as follows:

- A systematic review of clinical trials assessing bacopa found it had efficacy in improving memory and some aspects of cognition.
- An anti-inflammatory and antioxidant dietary carotenoid, astaxanthin is a protective component of cell membranes which has been reported to clinically improve cognitive functions.
- Phosphatidylserine is a key phospholipid constituent of cell membranes that is found in especially high concentrations in cerebral tissue; there is limited, preliminary evidence that phosphatidylserine may reduce the risk of cognitive dysfunction.
- Vitamin E deficiency is associated with Alzheimer's disease and MCI.

Patients (n = 104, aged ≥ 50 years) referred to 5 outpatient clinics in Italy for forgetfulness, disorientation, difficulty in concentrating, or other cognitive difficulties, and diagnosed with MCI were included. MCI diagnosis was based on a mini-mental state examination (MMSE) score of ≥ 22 and < 28 and on caregiver testimony on cognitive symptoms. Patients were excluded if they had known current psychiatric disorders or

organic diseases that could interfere with the cognitive status or were being treated with any psychotropic drug.

Patients took 1 tablet/day of Illumina for 60 days. Description of the Illumina tablet was restricted to the following information: 74 mg microalgae (*Haematococcus pluvialis*) dry extract 3%, 2 mg astaxanthin, 100 mg bacopa dry extract 20%, 20 mg bacosides, 30 mg phosphatidylserine extracted from soy (*Glycine max*), and 30 mg vitamin E of vegetable origin.

Cognition was assessed with the Alzheimer's Disease Assessment Scale-cognitive subscale (ADAS-cog) and Clock Drawing Test (CDT). ADAS-cog evaluates characteristics of cognitive efficiency that are sensitive to deterioration, and CDT examines planning ability and constructive skills.

No patient reported concomitant drug use that would affect cognitive status. There was a significant improvement in the ADAS-cog score and the CDT score from baseline to study end (P < 0.001 for both). There was a significant improvement on each of the 11 ADAS-cog test components ($P \le 0.02$ for all); the largest improvements were in word recall and word recognition (measures of memory). The largest ADAS-cog improvements were associated with the "less compromised baseline mini-mental state examination scores." A total of 16% of patients rated efficacy as excellent, 46% rated efficacy good, 28% rated efficacy fair, and 10% rated efficacy as poor/of no use.

One adverse event was reported (gastric disturbance), which led to the patient withdrawing from the study. The patient was also taking corticosteroids. A total of 67% of patients rated tolerability as excellent, 32% rated tolerability as good, and 1% rated tolerability as poor.

The authors conclude that Illumina improved cognitive and mnemonic skills in patients diagnosed with MCI. They acknowledge that the basic limitation of the trial is the lack of a control group and say that it should be regarded as an exploratory study. In the introduction, the authors note that data suggest that 25-30% of patients with MCI revert to normal spontaneously. This means that without a control group, there is no way of ascertaining how much of the improvement seen in the study would have occurred normally, without any supplements. Other noted limitations include the short observation period and lack of compliance assessment. The authors deem that "further investigation of this compound in adequately controlled, longer-term studies is warranted to formally assess its cognitive effects in mild or moderate mnemonic-cognitive disorders."

—Heather S. Oliff, PhD

Referenced article can be found at http://www.dovepress.com/cognitive-effects-of-a-dietary-supplement-made-from-extract-of-bacopa--peer-reviewed-article-NDT.