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## A Nutritional Formulation for Cognitive Performance and Mood in Alzheimer's Disease and Mild Cognitive Impairment: A Phase II Multi-site Randomized Trial with an Open-label Extension

Ruth Remington

*University of Massachusetts - Lowell*

*Et al.*

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# **A nutritional formulation for cognitive performance and mood in Alzheimer's disease and Mild Cognitive Impairment: a phase II multi-site randomized trial with an open-label extension**

Ruth Remington<sup>1\*</sup>, Cynthia Bechtel<sup>2§</sup>, David Larsen<sup>3§</sup>, Jevin J. Lortie<sup>4§</sup>, Annemarie Samar<sup>5§</sup>, Laura Doshanjh<sup>6</sup>, Paul Fishman<sup>6</sup>, Yuan Luo<sup>6\*\*</sup>, Kathleen Smyers<sup>1</sup>, Heather Hoffmann<sup>4</sup>, Constance Barysaukas<sup>7</sup>, Bruce Barton<sup>7</sup>, Thomas B. Shea<sup>1</sup>

<sup>1</sup>University of Massachusetts Lowell, Lowell, MA 01854, <sup>2</sup>Framingham State University, Framingham, MA 01701, <sup>3</sup>Advanced Memory Dynamics, Layton, UT 84040, <sup>4</sup>Knox College, Galesburg, IL 61401, <sup>5</sup>Worcester State University, Worcester, MA 01602, <sup>6</sup>University of Maryland, College Park, MD 20740, <sup>7</sup>University of Massachusetts Worcester, Worcester, MA 01655

**CONTACT:** TB Shea [Thomas\\_Shea@uml.edu](mailto:Thomas_Shea@uml.edu) 978-934-2881 Fax 978-934-3044

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## **ABSTRACT**

### **Background**

It is increasingly recognized that interventions for dementia must shift towards prevention to obtain maximal efficacy and any significant degree of disease modification. Nutritional supplementation with single agents has shown varied results, suggesting the need for combinatorial intervention.

### **Methods**

We conducted a 3-month, randomized, multi-site, phase II study in which 141 individuals diagnosed with Alzheimer's disease (AD) and 34 individuals with Mild Cognitive Impairment received a nutraceutical formulation (NF; folate, alpha-tocopherol, B12, S-adenosyl methionine, N-acetyl cysteine, acetyl-L-carnitine) or indistinguishable placebo under double-blind conditions, followed by an open-label extension in which all individuals received NF for a total of 1yr. An additional 38 individuals with AD received NF under open-label conditions from baseline for 1yr. The primary outcome was defined as cognitive performance. Secondary outcomes were defined as behavioral and psychological symptoms of dementia and activities of daily living.

### **Results**

Participants randomized to NF improved statistically within 3 months in cognitive performance as ascertained by Clox-1 and the Dementia Rating Scale, and their caregivers reported improvement in Neuropsychiatric Inventory. Participants receiving NF either continued to improve or maintained their baseline performance during open-label extensions. Participants randomized to placebo did not improve, but during open-label extensions displayed similar improvement within 3 months to that of participants initially randomized to NF. Caregivers reported no change in Activities of Daily Living for either cohort.

### **Conclusions**

These findings confirm and extend prior phase I studies in which NF improved or maintained cognitive performance and behavioral symptoms for individuals with AD, and improved cognitive performance for community-dwelling individuals without dementia.

In published studies with transgenic mice NF reduced PS-1 expression, beta and gamma secretase activity, Abeta deposits, phospho-tau, homocysteine and oxidative damage, and increased acetylcholine and glutathione. This comprehensive impact of NF on AD-related neuropathology supports the possibility that NF may harbor disease-modifying properties.