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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

Cynthia Bechtel
Framingham State University

David Larsen
Advanced Memory Dynamics

See next page for additional authors

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Presenter Information
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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 Remington1*, Cynthia Bechtel2§, David Larsen3§, Jevin J. Lortie4§, Annemarie Samar5§, Laura Doshanjh6, Paul Fishman6, Yuan Luo6**, Kathleen Smyers1, Heather Hoffmann4, Constance Barysauskas7, Bruce Barton7, Thomas B. Shea1

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

CONTACT: TB Shea 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.