

Nutritional intervention helps in mild Alzheimer's disease

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A second clinical trial of the medical food Souvenaid confirmed that daily intake of the nutritional intervention improves memory in people with mild Alzheimer's disease (AD). Results of the trial - called Souvenir II - were presented at the 4th International Conference on Clinical Trials in Alzheimer's Disease (CTAD) in San Diego, California on Friday, Nov. 4, 2011 by Philip Scheltens, MD, PhD, Professor of Cognitive Neurology and Director of the Alzheimer Center at the VU University Medical Center in Amsterdam.

CTAD is sponsored by the University of California, San Diego School of Medicine and the European Alzheimer's Disease Consortium (EADC).

Souvenaid contains a patented combination of nutrients (Fortasyn Connect) specifically designed to stimulate the formation of [nerve connections](#) called synapses. Loss of synapses is thought by many Alzheimer's experts to be the underlying cause of [memory](#) loss and cognitive dysfunction in AD. Preclinical studies showed that the nutrients in Fortasyn Connect promote the growth of new brain synapses. Subsequently, in a study called Souvenir I, Souvenaid taken once per day over 12 weeks was shown to improve scores on standardized memory tests.

"I'm encouraged by the results of this second trial, but we need to do more analyses and further studies to fully understand the findings," said Scheltens. "These positive results give me the energy to go forward."

Souvenir II, conducted at 27 centers in six European countries, was designed to confirm that the benefits seen in Souvenir I persist for 24 weeks. The study also used a more comprehensive measure of memory, as well as other measures of [brain activity](#). Participants in the blind study were randomly assigned to drink 125 ml. of Souvenaid or a control drink. Of the 259 subjects enrolled in the trial, 238 (91.9%) completed the study. Souvenaid was well tolerated, with 97% compliance among those who completed the study and a very favorable safety profile.

Memory performance was evaluated at baseline, 12 weeks and 24 weeks. The memory domain score of a Neuropsychological Test Battery (NTB) was the primary outcome parameter. This memory composite score was derived from the Rey Auditory Verbal Learning Test (immediate recall, delayed recall and recognition performance) and the Wechsler Memory Scale verbal paired associates test (immediate and delayed recall). Secondary outcomes resulting from the NTB were the executive function domain, total composite score and individual item scores.

During 24 weeks, memory composite scores from the Souvenaid group were significantly better than those from the control group. The significant effect on [memory performance](#) was confirmed by individual tasks of the NTB memory domain. Detailed analyses of secondary outcomes are still ongoing, including electroencephalogram (EEG) data as a measure of brain function. The EEG analysis, along with data from a magnetoencephalogram (MEG) sub-study may provide further understanding of the effect of Souvenaid on functional connectivity, thus investigating the hypothesis that Souvenaid can support synapse formation and function in mild AD.

Provided by University of California - San Diego

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