

Nutritional drink can help to conserve memory in case of prodromal Alzheimer's disease

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Professor Tobias Hartmann, Saarland University. Credit: Saarland University

The study did not find a significant benefit in broad cognitive function (the study primary endpoint). Cognitive decline over the study period was less than originally expected when it was designed ten years ago, so differences found between the two groups were too small to be statistically significant. Project coordinator Professor Tobias Hartmann, Saarland University Germany, explained that this is the most likely reason the primary endpoint was not met.

Professor Hilkka Soininen, Professor in Neurology MD, PhD from the University of Eastern Finland, who headed the clinical trial as part of the LipiDiDiet project, said: "Today's results are extremely valuable as they bring us closer to understanding the impact of nutritional interventions on prodromal AD which we are now better at diagnosing but unable to treat due to a

lack of approved pharmaceutical options.

The LipiDiDiet study illustrates that this nutritional intervention can help to conserve brain tissue and also memory and patients' ability to perform everyday tasks—possibly the most troubling aspects of the disease. We look forward to the results of subsequent analyses and the six year extension study which will provide further insights".

The clinical trial, headed by Professor Hilkka Soininen is part of a large EC project (LipiDiDiet) to explore the therapeutic and preventative impact of nutrition on neuronal and cognitive performance in ageing, AD and vascular dementia. LipiDiDiet is funded by the seventh Framework Programme (FP7) of the European Commission (EC) and coordinated by Professor Hartmann, Saarland University in Germany.

Fortasyn Connect was selected by a consortium of leading researchers from 19 European institutes, for this 24-month, randomised, controlled, double-blind, multicentre study involving 311 patients - on the basis of its results in a previous EU project (LipiDiet).

Nearly 47 million people have Alzheimer's or a related dementia for which there is currently no cure.² This number is expected to double every 20 years, reaching 74.7 million in 2030 and 131.5 million in 2050.²

Study details

The trial was the first to investigate the impact of Fortasyn Connect on patients with prodromal AD who were randomised to receive either Fortasyn Connect or an iso-caloric control drink once daily.

The primary outcome parameter was selected to

assess the effect on cognitive function (a broad measure of thinking) during 24 months intake of Fortasyn Connect compared with a control product. This was a cognitive composite score consisting of the CERAD 10-word immediate recall, delayed recall and recognition, category fluency and letter digit substitution test.

Secondary outcome parameters were brain volumes (total hippocampal, whole-brain & ventricular volumes), the Clinical Dementia Rating Sum of Boxes (CDR-SB), Neuropsychological Test Battery composite scores: episodic memory, executive function/working memory composite and a complete composite score consisting of 16 subtests, progression to (AD) dementia, blood and CSF biomarkers, tolerance and safety.

No significant difference was observed for the cognitive composite score. Predefined analyses showed significant differences between active and control study groups for hippocampal and whole-brain atrophy, and favourable effects for CDR Sum of Boxes and episodic memory (both were most pronounced in patients with high baseline cognition with regular intake). Analyses are ongoing for progression to (AD) dementia and blood and CSF biomarkers.

Tobias Hartmann, the project's coordinator, said "We have known for a while that diet can reduce the risk of developing dementia. Indeed, certain nutrients have been found to have a neuroprotective effect on the brain. However translating this into an effective intervention hasn't been easy because single nutrients simply aren't powerful enough to fight a disease like Alzheimer's alone. Today's clinical trial results have shown that the key is combining certain nutrients, in order to increase their effect.

This is exciting because it shows that in the absence of effective drug options, we really have found something that can help slow down some of the most distressing symptoms in prodromal AD; especially in those who started the intervention early. Indeed those patients who have lost the least cognitive function, have the most to gain".

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