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Alzheimer's preclinical staging criteria supported

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By Eleanor McDermid

The Alzheimer's disease (AD) preclinical staging criteria proposed by the National Institute on Aging and the Alzheimer's Association appear to be valid over more than a decade of follow-up, say researchers.

Their study shows that accelerated cognitive decline occurs only when cerebrospinal fluid levels of both β-amyloid (Aβ) and tau are abnormal.

Patients in stage 2 - with low Aβ and high tau levels - had a significantly larger cognitive decline than patients in stage 0 (high Aβ, low tau) during the study period, report Anja Soldan (Johns Hopkins University School of Medicine, Baltimore, Maryland, USA) and co-researchers in *JAMA Neurology*.

But the cognitive performance of patients in stage 1 (low Aβ, low tau) did not change over the average 11 years of follow-up.

In an accompanying editorial, Elizabeth Mormino and Kathryn Papp, from Massachusetts General Hospital in Boston, USA, say that the follow-up period "is dramatically longer" than in previous studies of these staging criteria.

"Therefore, the fact that significant decline does not emerge in stage 1 after such a prolonged follow-up period is an important consideration for clinical trials that select middle-aged participants based on biomarker data", they write.

The 222 study participants were drawn from the BIOCARD study cohort. They were aged an average of 56.9 years, which Mormino and Papp say is notably younger than in previous studies.

Global cognitive performance, ascertained from four standard tests of memory and executive function, was significantly reduced at baseline in the 28 participants classed as stage 2 relative to the 102 classed as stage 0, as well as declining more during follow-up.

This "suggests that clinical trials targeting stage 2 individuals may be able to detect meaningful cognitive decline at a much earlier age than previously expected", say the editorialists.

There were 46 patients classed as stage 1 and another 46 as SNAP (suspected non-AD pathology), with high Aβ and high tau. Neither group differed significantly from the stage 1 group in terms of cognition at baseline or during follow-up.

Notably, the increased cognitive decline in the stage 2 group was not further increased by possession of the *APOE* ε4 allele, despite it being more frequent in the stage 2 group than the other groups (50.0 vs 23.5-41.3%).

"Taken together, these 2 findings suggest that the *APOE* ε4 allele does not significantly alter the rate of AD progression but is associated with an earlier age at onset of AD", say the researchers.