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Alzheimer's prevention trial to evaluate, monitor participants' reactions to learning of higher disease risk status

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A new clinical trial will soon begin testing whether early medical intervention in people at risk for Alzheimer's can slow down progression of disease pathology before symptoms emerge, as outlined in *Science Translational Medicine*. For the first time, people with no Alzheimer's disease symptoms will be told of their risk status before being asked to join the randomized controlled trial. As part of the overall prevention trial, Penn Medicine neurodegenerative ethics experts will monitor how learning about their risk of developing Alzheimer's impacts trial participants.

Alzheimer's disease afflicts more than 13 percent of individuals over the age of 65, and remains one of the most feared consequences of aging.

"In order to ethically conduct a study where patients will learn they have a greater chance of developing Alzheimer's disease dementia, we've integrated continual assessments of potential participants throughout the process, to ensure that they are ready to receive information about their amyloid status and aren't having any adverse reactions after finding out," said Jason Karlawish, MD, professor of Medicine and Medical Ethics and Health Policy in the Perelman School of Medicine at the University of Pennsylvania and Associate Director of the Penn Memory Center.

Dr. Karlawish directs the Penn Neurodegenerative Disease Ethics and Policy Program. "This study is an important step in determining the

consequences of being tested for Alzheimer's disease before the person has disabling cognitive impairments."

The A4 trial requires that patients enrolled must have one of the pathologies typically seen in Alzheimer's disease dementia, which will be assessed using a brain PET scan that measures amyloid. Given that studies have shown that about one third of clinically normal older individuals have evidence of amyloid plaque accumulation but may not develop any cognitive symptoms within their lifetime, the patients who are enrolled in the trial based on positive amyloid results may or may not go on to develop Alzheimer's disease dementia.

"In addition to the study's primary aims - looking at whether early treatment can slow cognitive decline - we will carefully measure how disclosure impacts cognitive test performance, the perception of cognitive symptoms, quality of life and perceived risk of Alzheimer's in participants with and without evidence of amyloid accumulation," said Karlawish.

More information: "The A4 Study: Stopping AD before Symptoms Begin?," by R.A. Sperling et al. *Science Translational Medicine*, 2014. stm.sciencemag.org/content/6/228/228fs13.abstract

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