

Ginkgo Evaluation of Memory Study

at a glance

The GEM Study is a double-blinded placebo clinical trial study sponsored by the National Center for Complementary and Alternative Medicine, National Institute on Aging, National Heart, Lung, and Blood Institute, and the National Institute for Neurological Diseases and Stroke. The goal of this prevention trial is to find out if medicine made from the plant *Ginkgo biloba* can prevent or delay the changes in memory, thinking, and personality that can occur as people get older. Doctors refer to these changes as dementia, the most well known type being Alzheimer's disease. Between 2000 and 2001, the study enrolled 3074 people nationally. The Washington County field center enrolled 457 from surrounding areas within a 50-mile radius of Hagerstown, MD. Half are taking pills that contain *Ginkgo biloba*, and half are taking a "placebo" (pills that do not contain *Ginkgo biloba*). When the study has been completed, the two groups will be compared to see if there are differences in how memory, thinking, and personality have changed, and to see if *Ginkgo biloba* has been effective in preventing these changes.

Geographic areas and their respective field centers nationally include:

- Pittsburgh, PA – University of Pittsburgh
- Greensboro and Winston-Salem, NC – Wake Forest University
- Sacramento, CA - University of California at Davis
- Washington County, MD – The Johns Hopkins University

The study's Data Coordinating Center is at the University of Washington in Seattle, WA. The Diagnostic Coordinating Center is at the University of Pittsburgh. Wake Forest University is home to the study's Clinical Coordinating Center.

After completing a screening telephone interview, potential participants were evaluated at a screening clinic visit to determine cognitive and physical eligibility. Upon acceptance into the study, a baseline visit was conducted, followed by randomization to the study drug. Visits are scheduled every 6 months and continue to focus on measuring changes in cognitive function, memory, and personality with procedures such as a neuropsychological battery, the Modified Mini-mental State Exam (3MSE), and Alzheimers Disease Assessment Scale (ADAS-cog). An important component of the study has been for each participant to establish a proxy who has sufficient routine contact with the participant to vouch for her/his cognitive status, memory function, and personality changes. Both the participant and proxy participate in Cognitive Dementia Rating interviews held at each visit. Visits are scheduled in the clinic, in the home, or by phone if necessary. Upon documentation of cognitive decline, a neuro exam is performed by a neurologist, followed by a cranial MRI or CT scan. These results are then reviewed to determine appropriateness of study continuance. Between clinic visits, phone calls are made to participants at 3-month intervals to determine any new health or life events. Serious adverse events are monitored to document events that may jeopardize the well-being of the study participants.

The current Principal Investigator is Linda Fried, MD, MPH, lfried@jhmi.edu
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For more information, visit the GEM public website at <http://www.nccam-ginkgo.org>