Important Clarification of New *Ginkgo biloba* Study

Medical Editor’s Note: Typically the *Natural Medicine Journal* would not likely use commentary on a study featuring only previously published data; however, because of the national media attention and need for clarification, we contacted botanical expert Mark Blumenthal to comment on the recent analysis published by Snitz et al.

**Commentary by:** Mark Blumenthal


**Design:** This was an analysis of outcomes from the randomized, double-blind, placebo-controlled Ginkgo Evaluation of Memory (GEM) clinical trial previously published.¹

**Participants:** The GEM study featured 3,069 community-dwelling participants aged 72 to 96. Study was conducted in 6 academic medical centers in the United States from 2000 to 2008. The median follow-up was 6.1 years. Participants were given either 120 mg standardized extract of leaves of *Ginkgo biloba* (EGb 761®, W. Schwabe Pharmaceuticals, Karlsruhe, Germany – the world’s most clinically documented ginkgo extract) twice daily or placebo. Outcome measures included rates of change over time in the Modified Mini-Mental State Examination (EMSE), changes in cognitive subscale of the Alzheimer Disease Assessment Scale (ADAS-Cog), and changes in neuropsychological domains of memory, attention, visual-spatial construction, language, and executive functions, based on sums of z scores of individual tests.

**Objective:** The objective of the original GEM study was to determine whether taking ginkgo would prevent the onset of dementia. The new analysis by Snitz and colleagues attempted to detect the possible decline in levels of cognitive function, which was not a primary outcome measure of the GEM study.

**Key Findings:** Both the GEM study and the recent analysis demonstrate the general safety of ginkgo extract. The amount of adverse events was basically the same in
both the ginkgo and placebo groups with no serious adverse effects (e.g., no statistically significant incidence of coronary heart disease, stroke, or major bleeding).

The previously published GEM study found that ginkgo was not effective in reducing the incidence of Alzheimer dementia. The new publication found that compared with placebo, taking ginkgo extract did not result in less cognitive decline in older adults with normal cognition or those with mild cognitive impairment.

**Study Limitations:** Under my direction, the American Botanical Council, an independent nonprofit research and education organization, has identified the following limitations of the recent publication by Snitz and colleagues:

- As mentioned, the data published last week are drawn from a previous clinical trial which was not designed to determine the decline in cognition.

- About 40% of the subjects dropped out over the 6.1-year duration of the trial; the statistics reported in the study include the dropouts for which no final data are available.

- The subjects in the study were not monitored for certain cognitive parameters until several years after the trial began, creating difficulty in determining accurately whether they experienced a decline in cognition or not.

- The age of the subjects is quite advanced, at an average of 79 years at the beginning of the trial. This age group is not typical of the age of both healthy people and those with mild cognitive impairment who use ginkgo for improving mental performance.

- There is also a lack of an active control, a potential third arm of the trial (i.e., besides the patients on ginkgo or placebo) in which patients would have used a pharmaceutical medication with presumed efficacy, to determine to what extent the particular population being tested would respond. This was not possible for this trial since no conventional pharmaceutical drug has ever demonstrated the ability to prevent the onset of dementia or diminish its progression.

**Previous Research:** Several recent publications have demonstrated an improvement in cognitive performance in subjects using the same German gingko extract. At least 16 controlled clinical trials have evaluated various ginkgo extracts for healthy, non-cognitively impaired adults. A systematic review has shown that in 11 of these trials, ginkgo increased short-term memory, concentration and time to process mental tasks.

**Clinical Implications:** Given the limitations of the recent JAMA study published by Snitz and colleagues, the results must be viewed in proper perspective. There is a vast body of pharmacological and clinical research supporting numerous health
benefits for ginkgo extracts, particularly for improving various symptoms and conditions associated with declining cognitive performance and poor circulation. This trial is not conclusive nor should it in any way detract from ginkgo’s reputation as a useful dietary supplement to help support and improve cognitive function and enhance peripheral circulation—conditions for which it has been reported to be effective in numerous clinical trials.

About The Author

Mark Blumenthal is the Founder and Executive Director of the American Botanical Council (www.herbalgram.org). Mark is a frequent speaker and panelist at university, professional and industry conferences. His former involvement in the herb industry included roles as President of the Herb Trade Association and a founding board member of the American Herbal Products Association. He is the Editor/Publisher of HerbalGram, and is the senior editor of the English translation of The Complete German Commission E Monographs -- Therapeutic Guide to Herbal Medicines. He is also the senior editor of The ABC Clinical Guide to Herbs.


