

Health & Nutrition Letter

THE FRIEDMAN SCHOOL OF NUTRITION SCIENCE AND POLICY

YOUR GUIDE TO LIVING HEALTHIER LONGER ■ FEBRUARY 2010, Volume 27, Number 12, \$5

Ginkgo Fails to Prevent Heart Attacks or Strokes

But study suggests possible benefit against PAD.

The herbal treatment ginkgo biloba struck out in another major test, this time of its purported ability to prevent heart attacks and strokes. But researchers were surprised by a possible benefit of ginkgo in preventing peripheral artery disease (PAD).

Lewis H. Kuller, MD, DrPH, of the University of Pittsburgh and colleagues, who in 2008 found no benefit for ginkgo in preventing dementia, reported new findings from the randomized, 3,069-patient Ginkgo Evaluation of Memory Study. As part of the study, researchers also assessed the herb's role in preventing cardiovascular disease.

Participants received either 120 milligrams of a highly purified form of ginkgo biloba or placebo twice daily. More than half of the participants, who averaged age 79, had high blood pressure and a quarter had a history of cardiovascular disease. Over a six-year period, 385 patients died, 164 were hospitalized with heart attacks, 151 had strokes, 73 had transient ischemic attacks ("mini-strokes") and 207 experienced chest pain. Researchers found no significant differences between the ginkgo biloba and placebo groups in any of these outcomes.

Of the 35 study participants treated for PAD, however, 23 were in the placebo

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Lifestyle Changes Produce Lasting Benefit Against Diabetes Risk

A long-term followup to the Diabetes Prevention Program trial has good news for the estimated 57 million Americans with high blood-sugar levels that put them in danger of developing diabetes: Intensive lifestyle changes aimed at modest weight loss reduced the rate of developing type 2 diabetes by 34% compared with a control group in people at high risk for the disease. Reducing dietary fat and calories, exercising such as walking about 150 minutes weekly and losing weight also proved more effective in diabetes prevention than metformin, an oral diabetes drug.

"In 10 years, participants in the lifestyle-changes group delayed type 2 diabetes by about four years compared with placebo, and those in the metformin group delayed it by two years," said study chair David M. Nathan, MD, of Massachusetts General Hospital. "The benefits of intensive lifestyle changes were especially pronounced in the elderly. People age 60 and older lowered their rate of developing type 2 diabetes in the next 10 years by about half."

The results of the Diabetes Prevention Program Outcomes Study (DPPOS) were published in *The Lancet*. The DPPOS is a continuation of the Diabetes Prevention Program (DPP), a large, randomized trial in 3,234 overweight or obese adults, average age 51, with elevated blood glucose levels. Nearly half represented minority groups disproportionately affected by type 2 diabetes.

Researchers announced the initial DPP findings in 2001—a year earlier than scheduled—because the results were so clear: After three years, intensive lifestyle changes reduced the development of type 2 diabetes by 58% compared with placebo. That was nearly double the relative benefit seen for a second study group receiving 850 milligrams daily of metformin.

Other studies have shown that diet and exercise delay type 2 diabetes in at-risk people. But the DPP, conducted at 27 health centers nationwide by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), part of the National Institutes of Health, was the first major trial to show that lifestyle changes can effectively delay diabetes in a diverse population of overweight American adults at high risk of diabetes.

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Diabetes

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Striking as the findings were, researchers could not say how long the benefit would last, since the results were based on just three years of data. After a six-month interim in which all participants were offered help with diet and exercise, 88% agreed to continue in a followup study.

Annual diabetes incidence in all three original groups was roughly the same over the next seven years, as both the metformin and placebo participants tried lifestyle changes and weight loss. The percentage of those groups annually developing diabetes fell to match the 5%-6% rate of the lifestyle group, which remained steady throughout the DPPOS. The three-year head start of the lifestyle-changes group persisted, however, with long-term lower diabetes incidence than other participants.

In the first year of the original study, the lifestyle group lost an average of 15 pounds of body weight. Over 10 years, however, they regained all but about 5 pounds. The placebo group lost less than 2 pounds over the decade.

Ginkgo

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group versus 12 receiving ginkgo—a statistically significant difference, researchers noted.

“Clearly you can’t make a national recommendation based on these numbers, but the data is intriguing,” Dr. Kuller said.

“Peripheral artery disease is a major public health problem and the preventive therapies are not very good. My feeling is that ginkgo and its class of agents, flavonoids, should

A pilot YMCA-based program to bring the findings of the DPP study to the public may soon take off nationwide. The program, involving about 350 participants at a dozen YMCAs in Indiana, Kentucky and Minnesota, trains people at risk for diabetes in nutrition and exercise. After an initial 16-week course, modeled on the successful lifestyle intervention in the DPP, participants receive monthly followup support. The Centers for Disease Control and Prevention (CDC), which has spent \$3 million on the pilot project, recently opened a center at Emory University to set standards and train master instructors to expand the program.

“Sustaining even modest weight loss with lifestyle changes is highly challenging, but it produced major long-term health rewards by lowering the risk of type 2 diabetes and reducing other cardiovascular risk factors in people at high risk of developing diabetes,” said lead author and a principal investigator for the study,

be further evaluated to see if they have some benefit.”

Ginkgo biloba contains a class of antioxidant nutrients—flavonoids—found in fruits, vegetables, dark chocolate and red wine, which are believed to offer some protection against cardiovascular events.

About 8 million Americans suffer from peripheral artery disease, although many don’t know it because the symptoms are often mistaken for something else. The most common symptoms of PAD are

William Knowler, MD, DrPH, of the NIDDK in Phoenix. “Once we learned how dramatically this intervention reduced diabetes onset in the DPP, we offered modified training in lifestyle changes to all participants, which probably contributed to the falling diabetes rates in the placebo and metformin groups.”

Participants in the lifestyle group saw lower blood pressure and triglyceride levels, despite taking fewer drugs to control their heart disease risk.

“The spiraling epidemics of obesity and type 2 diabetes in United States and worldwide show no signs of abating,” commented Griffin P. Rodgers, MD, director of the NIDDK. “Millions of people could delay diabetes for years and possibly prevent the disease altogether if they lost a modest amount of weight through diet and increased physical activity.”

TO LEARN MORE: *The Lancet*, Nov. 14, 2009; abstract at <[dx.doi.org/10.1016/S0140-6736\(09\)61457-4](http://dx.doi.org/10.1016/S0140-6736(09)61457-4)>. DPP/DPPOS <www2.niddk.nih.gov/Research/ClinicalResearch/DPPOS>. National Diabetes Education Program, (301) 498-3583, <ndep.nih.gov>. ♦

cramping, pain or tiredness in the leg or hip muscles while walking or climbing stairs. Typically, this pain goes away with rest and returns when you walk again. People with PAD are at higher risk for heart attack and stroke and, left untreated, PAD can lead to gangrene and amputation.

TO LEARN MORE: *Circulation: Cardiovascular Quality and Outcomes*, online before print; abstract at <dx.doi.org/10.1161/CIRCOUTCOMES.109.871640>. About PAD <www.americanheart.org/presenter.jhtml?identifier=3020242>. ♦

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The Friedman School gratefully
acknowledges ongoing support for
research and education from John
Hancock Financial Services, Inc.



Tufts University Health & Nutrition
Letter (ISSN 1526-0143) is published
monthly for \$36 per year by Tufts
University. Managed by Belvoir Media
Group, LLC.
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Send address corrections to PO Box 8517,
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