

The Diabetes Prevention Program

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From 1998 until 2001, Dr. Hayward participated as one of the investigators in the Diabetes Prevention Program (DPP), a major nationwide study that concluded that diet and exercise delayed the onset of Type 2 Diabetes. The study also found that treatment with the oral diabetes drug metformin (Glucophage®) also reduces diabetes risk, though less dramatically than diet and exercise, in people at high risk for Type 2 Diabetes. The study ended one year early because of its dramatic findings.

As described in the press release issued by the United States National Institute of Diabetes & Digestive & Kidney Diseases of the National Institutes of Health (NIDDK):

“The Diabetes Prevention Program (DPP), was a major clinical trial in 3,234 people with impaired glucose tolerance, a condition that often precedes diabetes. The study compared (1) intensive lifestyle changes consisting of diet and exercise; (2) treatment with the oral diabetes drug metformin; and (3) placebo (a control group that took placebo pills in place of metformin). The second and third groups also received standard information on diet and exercise.

“Participants randomly assigned to intensive lifestyle intervention reduced their risk of getting type 2 diabetes by 58 percent. On average, this group maintained their physical activity at 30 minutes per day, usually with walking or other moderate intensity exercise, and lost 5-7 percent of their body weight. Participants randomized to treatment with metformin reduced their risk of getting type 2 diabetes by 31 percent.

“On the advice of the DPP’s external data monitoring board, the trial ended a year early because the data had clearly answered the main research questions.

“Smaller studies in China and Finland have shown that diet and exercise can delay type 2 diabetes in at-risk people, but the DPP, conducted at 27 centers nationwide, is the first major trial to show that diet and exercise can effectively delay diabetes in a diverse American population of overweight people with impaired glucose tolerance (IGT). IGT is a condition in which blood glucose levels are higher than normal but not yet diabetic. (See also Diabetes Prevention Program: Questions & Answers.)

“Lifestyle intervention worked as well in men and women and in all the ethnic groups. It also worked well in people age 60 and older, who have a nearly 20 percent prevalence of diabetes, reducing the development of diabetes by 71 percent. Metformin was also effective in men and women and in all the ethnic groups, but was relatively ineffective in the older volunteers and in those who were less overweight,’ said DPP study chair Dr. David Nathan of Massachusetts General Hospital, Boston.

“DPP volunteers were randomly assigned to one of the following groups:

- intensive lifestyle changes with the aim of reducing weight by 7 percent through a low-fat diet and exercising for 150 minutes a week.
- treatment with the drug metformin (850 mg twice a day), approved in 1995 to treat type 2 diabetes.
- a standard group taking placebo pills in place of metformin.

The latter two groups also received information on diet and exercise.

“DPP participants ranged from age 25 to 85, with an average age of 51. Upon entry to the study, all had impaired glucose tolerance as measured by an oral glucose tolerance test, and all were overweight, with an average body mass

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index (BMI) of 34. About 29 percent of the DPP standard group developed diabetes during the average follow-up period of 3 years. In contrast, 14 percent of the diet and exercise arm and 22 percent of the metformin arm developed diabetes. Volunteers in the diet and exercise arm achieved the study goal, on average a 7 percent — or 15-pound — weight loss, in the first year and generally sustained a 5 percent total loss for the study's duration. Participants in the lifestyle intervention arm received training in diet, exercise (most chose walking), and behavior modification skills.

“Can the interventions prevent diabetes altogether? ‘We simply don’t know how long, beyond the 3-year period studied, diabetes can be delayed,’ says Dr. Nathan. ‘We hope to follow the DPP population to learn how long the interventions are effective.’ The researchers will analyze the data to determine whether the interventions reduced cardiovascular disease and atherosclerosis, major causes of death in people with type 2 diabetes.

“Every year a person can live free of diabetes means an added year of life free of the pain, disability, and medical costs incurred by this disease,’ said Dr. Allen Spiegel, director of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), which sponsored the DPP. ‘The DPP findings represent a major step toward the goal of containing and ultimately reversing the epidemic of type 2 diabetes in this country.’

“Diabetes afflicts more than 16 million people in the United States. It is the main cause of kidney failure, limb amputations, and new onset blindness in adults and a major cause of heart disease and stroke. Type 2 diabetes accounts for up to 95 percent of all diabetes cases. Most common in adults over age 40, type 2 diabetes affects 8 percent of the U.S. population age 20 and older. It is strongly associated with obesity (more than 80 percent of people with type 2 diabetes are overweight), inactivity, family history of diabetes, and racial or ethnic background. Compared to whites, black adults have a 60 percent higher rate of type 2 diabetes and Hispanic adults have a 90 percent higher rate.

“The prevalence of type 2 diabetes has tripled in the last 30 years, and much of the increase is due to the dramatic upsurge in obesity. People with a BMI of 30 or greater have a five-fold greater risk of diabetes than people with a normal BMI of 25 or less.”