



Diabetes Prevention Program Fact Sheet



The Diabetes Prevention Program (DPP) was a major clinical trial, or research study, aimed at discovering whether either diet and exercise or the oral diabetes drug metformin could prevent or delay the onset of type 2 diabetes in people with impaired glucose tolerance (IGT).

The answer is yes. In fact, the DPP found that over the three years of the study, diet and exercise sharply reduced the chances that a person with IGT would develop diabetes. Metformin also reduced risk, although less dramatically. The DPP resolved these questions so quickly that, on the advice of an external monitoring board, the program was halted a year early. The researchers published their findings in the February 7, 2002, issue of the *New England Journal of Medicine*.

DPP Study Design and Goals

In the DPP, participants from 27 clinical centers around the country were randomly split into different treatment groups. The first group, called the lifestyle intervention group, received intensive intervention in diet, exercise, and behavior modification. By eating less fat and fewer calories and exercising for a total of 150 minutes a week, they aimed to lose 7 percent of their body weight and maintain that loss.

The second group took 850 mg of metformin twice a day. The third group received placebo pills instead of metformin. The metformin and placebo groups also received information on diet and exercise, but no intensive intervention. A fourth group was treated with the drug troglitazone (Rezulin), but this part of the study was discontinued after researchers discovered that troglitazone can cause serious liver damage.

All 3,234 study participants were overweight and had IGT, which are well recognized risk factors for the development of type 2 diabetes. In addition, 45 percent of the participants were from minority groups—African American, Hispanic American/Latino, Asian American or Pacific Islander, or American Indian—that are at increased risk of developing diabetes.

Type 2 Diabetes and Pre-Diabetes

Diabetes is a disorder that affects the way your body uses food for growth and energy. Normally, the food you eat is broken down into glucose. The glucose then passes into your bloodstream, where it is used by your cells for growth and energy. For glucose to reach your cells, however, insulin must be present. Insulin is a hormone produced by your pancreas, a hand-sized gland behind your stomach.

Most people with type 2 diabetes have two problems: the pancreas may not produce enough insulin, and fat, muscle, and liver cells cannot use it effectively. This means that

glucose builds up in the blood, overflows into the urine, and passes out of the body—without fulfilling its role as the body's main source of fuel.

About 23.6 million people in the United States have diabetes. Of those, almost 18 million are diagnosed and 5.7million are undiagnosed. Ninety to 95 percent of people with diabetes have type 2 diabetes. Diabetes is the main cause of kidney failure, limb amputation, and new-onset blindness in American adults. People with diabetes are also two to four times more likely than people without diabetes to develop heart disease.

Pre-diabetes, also called impaired glucose tolerance (IGT) or impaired fasting glucose (IFG), is a condition in which your blood glucose (blood sugar) levels are higher than normal **but not high enough for a diagnosis of diabetes**. Having pre-diabetes puts you at higher risk for developing type 2 diabetes. If you have pre-diabetes, you are also at increased risk for developing heart disease and stroke.

You are more likely to develop type 2 diabetes if

- you are overweight
- you are 45 years old or older
- you have a parent, brother, or sister with diabetes
- your family background is African American, American Indian, Asian American, Hispanic American/Latino, or Pacific Islander
- you have had gestational diabetes or gave birth to at least one baby weighing more than 9 pounds
- your blood pressure is 140/90 or higher, or you have been told that you have high blood pressure
- your HDL cholesterol is 35 or lower, or your triglyceride level is 250 or higher
- you are fairly inactive, or you exercise fewer than three times a week
- you have polycystic ovary syndrome (PCOS)
- you have blood vessel problems affecting the heart, brain or legs
- you have dark, thick and velvety patches of skin around your neck and armpits (This is called acanthosis nigricans, A-can-THO-sis NI-gri-cans.)

Pre-diabetes is becoming more common in the United States, according to new estimates provided by the U.S. Department of Health and Human Services. From 2003 to 2006, 25.9 percent of U.S. adults aged 20 or older had IFG. Applying this percentage to the entire U.S population in 2007 results in an estimate of 57 million American adults with pre-diabetes. Those with pre-diabetes are likely to develop type 2 diabetes within 10 years, unless they take steps to prevent or delay diabetes. The results of the Diabetes Prevention Program showed that modest weight loss and regular exercise can prevent or delay type 2 diabetes.

DPP Results

The DPP's striking results tell us that millions of high-risk people can modify their diet and exercise to lose a small amount of weight to delay or prevent the development of type 2 diabetes. The DPP also suggests that metformin is effective in delaying the onset of diabetes in younger, heavier people.

Participants in the lifestyle intervention group—those receiving intensive counseling on effective diet, exercise, and behavior modification—reduced their risk of developing diabetes by 58 percent. This finding was true across all participating ethnic groups and for both men and women. Lifestyle changes worked particularly well for participants aged 60 and older, reducing their risk by 71 percent. About 5 percent of the lifestyle intervention group developed diabetes each year during the study period, compared with 11 percent in those who did not get the intervention. Researchers believe that weight loss—achieved through better eating habits and exercise—reduces the risk of diabetes by improving the ability of the body to use insulin and process glucose.

Participants taking metformin reduced their risk of developing diabetes by 31 percent. Metformin was effective for both men and women, but it was least effective in people aged 45 and older. Metformin was most effective in people 25 to 44 years old and in those with a body mass index of 35 or higher (at least 60 pounds overweight). About 7.8 percent of the metformin group developed diabetes each year during the study, compared with 11 percent of the group receiving the placebo.

The National Diabetes Education Program (NDEP)—a joint project of the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and more than 200 public and private organizations—is disseminating the DPP findings and intervention strategies. ([link to Small Steps. Big Rewards](#))

Future Research

Diabetes Prevention Program Outcomes Study

The Diabetes Prevention Program Outcomes Study – or the DPPOS (2002 - present) – is a follow-up to the DPP to determine the longer-term effects of the original treatment interventions. This will provide further information regarding the impact of lifestyle intervention on diabetes onset and the incidence of cardiovascular disease.

Preliminary results of the DPPOS found that nearly 8 percent of participants with pre-diabetes in the DPP had diabetic eye disease (retinopathy). Diabetic eye disease was also seen in 12.6 percent of participants with type 2 diabetes who developed diabetes during the DPP. These findings suggest that patients with pre-diabetes or newly diagnosed type 2 diabetes should be screened for retinopathy.

HEALTHY

The HEALTHY study, a middle school program for diabetes prevention, sponsored by the National Institutes of Health began in 2006 to test a program to lower risk factors for type 2 diabetes in middle school students at 42 schools in 7 sites across the US. Participating schools were randomly assigned to an intervention group, which implements the behavior change activities, or to a control group, which continues to offer food choices and physical education programs typically seen in middle schools across the country. Students in the intervention group have

- healthier choices from the cafeteria and vending machines (e.g., lower fat foods, more fruits and vegetables, and drinks with no added sugar)
- longer, more intense periods of physical activity, and
- activities and awareness campaigns that promote long-term healthy behaviors.

After 2.5 years, all students will be tested for diabetes risk factors, including blood levels of glucose, insulin, and lipids. They also will be measured for fitness level, blood pressure, height, weight, and waist circumference. Results from the HEALTHY study are expected in 2009.

For more information about preventing and controlling diabetes, call 1-888-693-NDEP (6337) or visit the National Diabetes Education Program's website at www.YourDiabetesInfo.org.

NIH Publication No. 06-5099
July 2008