Diabetes Prevention Program

National Diabetes Information Clearinghouse

National Institute of Diabetes and Digestive and Kidney Diseases

NATIONAL INSTITUTES OF HEALTH

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 (Glucophage) 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 3 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 training 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 counseling efforts. 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 digested 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,

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

About 20.8 million people in the United States have diabetes. Of those, 14.6 million are diagnosed and 6.2 million 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.

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

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. About 40 percent of U.S. adults ages 40 to 74—or 41 million people—had pre-diabetes in 2000. New data suggest that at least 54 million U.S. adults had pre-diabetes in 2002. 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 use diet, exercise, and behavior modification to avoid developing type 2 diabetes. The DPP also suggests that metformin is effective in delaying the onset of diabetes.

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 think

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.

Future Research

Researchers will perform other analyses to try to determine the relative contribution of diet and exercise to the reduction in diabetes. The DPP was not designed to examine diet versus exercise, however, so the analyses may not provide a definitive answer. Researchers will also analyze the information from the study to try to determine how lifestyle intervention and metformin affect the development of heart and blood vessel diseases, which are more common in people with pre-diabetes and type 2 diabetes.

The DPP did not examine whether combining lifestyle changes and metformin would further reduce the risk of developing diabetes.

DPP researchers plan to continue examining the roles of lifestyle and metformin in preventing type 2 diabetes. They will also continue to monitor participants to learn more about the study's long-term effects. The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is encouraging new research to look at cost-effective methods of delivering lifestyle modifications in group settings and over the Internet, as well as methods to sustain behavior change and weight loss. 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—will disseminate the findings and protocols stemming from the DPP.

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The National Diabetes Information Clearinghouse (NDIC) is a service of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The NIDDK is part of the National Institutes of Health under the U.S. Department of Health and Human Services. Established in 1978, the Clearinghouse provides information about diabetes to people with diabetes and to their families, health care professionals, and the public. The NDIC answers inquiries, develops and distributes publications, and works closely with professional and patient organizations and Government agencies to coordinate resources about diabetes.

Publications produced by the Clearinghouse are carefully reviewed by both NIDDK scientists and outside experts. This fact sheet was reviewed by David M. Nathan, M.D., Massachusetts General Hospital.

This fact sheet is also available at *www.diabetes.niddk.nih.gov.*

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