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.

Nearly 25.8 million people in the United States have diabetes. Of those, 18.8 million are diagnosed and 7 million are undiagnosed. Type 2 diabetes accounts for 90 to 95 percent of diagnosed diabetes in adults. Diabetes is the leading cause of kidney failure, non-traumatic lower-limb amputation, and new cases of blindness among adults in the United States. 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 levels are higher than normal **but not high enough for a diagnosis of diabetes**. Having pre-diabetes puts you at higher risk of developing type 2 diabetes, heart disease and stroke. In addition to IGT and IFG, other factors that make it more likely a person will develop type 2 diabetes include:

- having a family history of diabetes
- being a member of an ethnic/racial group like African Americans, Hispanic/Latinos, Asian Americans, Pacific Islanders, American Indians, and Alaska Natives
- being overweight or obese being age 45 or older
- women who had gestational diabetes (diabetes diagnosed during pregnancy) or a baby weighing 9 pounds or more at birth
- having high blood pressure
- having abnormal cholesterol (lipid) levels
- not getting enough physical activity
- having polycystic ovary syndrome (PCOS)
- having blood vessel problems affecting the heart, brain or legs
- having dark, thick and velvety patches of skin around your neck or armpits (acanthosis nigricans)

Pre-diabetes is becoming more common in the United States, according to new estimates from the U.S. Department of Health and Human Services. From 2005 to 2008, based on fasting glucose or A1C levels, 35 percent of U.S. adults aged 20 years or older had pre-diabetes (50 percent of those age 65 years or older). Applying this percentage to the entire U.S population in 2010 yields an estimated 79 million Americans aged 20 and older with pre-diabetes. The percentage of U.S. adults aged 20 years or older with pre-diabetes in 2005-2008 was similar for non-Hispanic whites (35 percent), non-Hispanic Blacks (35 percent), and Mexican Americans (36 percent.)

The results of the Diabetes Prevention Program showed that people with pre-diabetes who lose weight and increase their physical activity 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 initiative 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.

Diabetes Prevention Program Outcomes Study

The Diabetes Prevention Program Outcomes Study (DPPOS), the 10-year follow-up study to the DPP, has closely followed 88 percent of the surviving DPP participants who were eligible to join. The DPPOS was designed to examine the longer-term impact of the original treatment interventions. Results of the DPPOS indicate that the effects of the DPP have persisted for years. The incidence of diabetes in the 10-year follow-up study was reduced by 43 percent in the lifestyle group, and 18 percent in those taking metformin compared with the placebo group. For participants age 60 and older, the development of diabetes was reduced by 49 percent by intensive lifestyle when compared to placebo. After an average of 10 years' follow up, treatment with metformin reduced the rate of developing diabetes by 18 percent compared with placebo.

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.

Other Research

The HEALTHY study was an intervention in middle schools to lower obesity rates to prevent type 2 diabetes. Findings from 2010 reported lower obesity rates in eight grade students at highest risk for type 2 diabetes who were initially found to be overweight or obese in sixth grade. However, schools that implemented the program did not differ from comparison schools in the study's primary outcome—the prevalence of overweight and obesity combined—which had declined 4 percent in both groups of schools by the end of the three-year study.

For children and teens at risk, making healthy lifestyle changes as a family may lower the risk for, delay or prevent the onset of type 2 diabetes. New research findings will help determine effective ways to lower risk factors in high risk children and their families.

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

Sources:

1. Diabetes Prevention Program Research Group. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin.N Engl J Med 2002; 346:393-403.

2. Centers for Disease Control and Prevention: National diabetes fact sheet: national estimates and general information on diabetes and pre-diabetes in the United States. Atlanta, GA: US Department of Health and Human Services, Centers for Disease Control and Prevention, 2011.

3. Diabetes Prevention Program Research Group (2009). "10-year follow-up of diabetes incidence and weight loss in the Diabetes Prevention Program Outcomes Study" available at http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2809%2961457-4/fulltext#

4. Diabetes Prevention Program Research Group. The prevalence of retinopathy in impaired glucose tolerance and recent-onset diabetes in the Diabetes Prevention Program. Diabetic Medicine 2007; 24(2);137-144.

5. The Healthy Study Group. A School-Based Intervention for Diabetes Risk Reduction. N Engl J Med 2010

May 2011