

**National Institute of Diabetes and Digestive and Kidney Diseases
(NIDDK)/National Institutes of Health (NIH): Diabetes Prevention
Program (DPP) and DPP Outcomes Study**

NIH-supported investigators found in a clinical trial that type 2 diabetes could be prevented or delayed in people at high risk of the disease. A lifestyle intervention of diet, exercise, and behavior modification was most effective at diabetes prevention, especially in older Americans. Ongoing research with the clinical trial participants is revealing more information about diabetes risk, onset, prevention, and outcomes.

Lead Agency:

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)/National Institutes of Health (NIH)

Agency Mission:

- Conduct and support basic, clinical, and translational research on diseases of internal medicine and related subspecialty fields, including diabetes and other endocrine and metabolic diseases; liver and other digestive diseases; nutritional disorders; obesity; kidney and urologic diseases; and hematologic diseases; as well as fundamental research in many basic science disciplines.
- Foster research training and mentoring at multiple career stages to maintain pipeline of outstanding investigators in these research fields.
- Disseminate science-based knowledge gained from NIDDK-funded research to health care providers and the public through outreach and communications.

Principal Investigators:

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Partner Agency:

NIDDK
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
National Institute on Aging (NIA)
National Eye Institute (NEI), National Center on Minority Health and Health Disparities(NCMHD)
NIH Office of Research on Women's Health (ORWH)
NIH Office of Behavioral and Social Sciences Research (OBSSR)

Indian Health Service (IHS)
Centers for Disease Control and Prevention (CDC)
National Heart, Lung, and Blood Institute (NHLBI)
Non-federal funding partners: Warner-Lambert (WL)
Bristol-Meyers Squibb (BMS)
American Diabetes Association (ADA)
National Center for Research Resources (NCRR)
Merck & Co.
Hoechst Merion Roussel
Sankyo
Life Scan
Slim Fast
Health-o-meter

General Description:

Diabetes Prevention Program (DPP) and DPP Outcomes Study

Understanding and preventing type 2 diabetes and its health complications is an important public health goal being addressed by NIH-supported research. Researchers continue to gain new insights into type 2 diabetes and its prevention from the landmark Diabetes Prevention Program (DPP) clinical trial and the follow up DPP Outcomes Study. The DPP was a randomized, controlled clinical trial that examined the effects of lifestyle and medical interventions on the development of type 2 diabetes in over 3,200 adults at risk for this disease. The DPP compared intensive lifestyle modification, treatment with the medication metformin, and standard medical advice. Published in 2002, the striking results of the DPP trial tell us that millions of high-risk people can use diet, exercise, and behavior modification to avoid or delay developing type 2 diabetes. In its most dramatic result, participants in the DPP 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, in fact best, for participants aged 60 or older, reducing their risk by 71 percent. The DPP also found that metformin is effective in delaying the onset of diabetes, but the study suggests it works best in younger, more overweight individuals and was much less effective in those over 60.

During the study, the DPP collected a broad array of health data and biological samples from the large, racially and ethnically diverse group of participants—some of whom developed diabetes during the course of the trial. This tremendous diabetes research resource is supporting informative analyses of diabetes risk factors and disease development. For example, recent analyses of DPP data have shown that steps taken to prevent or delay type 2 diabetes can also apparently help reduce risk factors for diabetes complications. In one study, it was found that hypertension, a classic risk factor for cardiovascular disease, was present in nearly one third of all DPP participants at the beginning of the trial, and increased in the patients who received either placebo or metformin—however, it significantly decreased in the lifestyle intervention group. The DPP data and samples have also enabled researchers to examine the influence of genetic

risk factors for type 2 diabetes on progression to disease in trial participants, and to investigate more readily the possible biological mechanisms associated with genetic risk.

Currently, the majority of DPP participants are being followed in the “DPP Outcomes Study” (DPPOS). The DPPOS is examining longer-term effects of the trial interventions on prevention of type 2 diabetes and its health complications—including heart disease, eye and kidney disease, and nerve damage. The DPPOS will also compare outcomes for women and men, and by age and ethnicity.

Excellence: What makes this project exceptional?

The Diabetes Prevention Program clinical trial is the largest and most racially and ethnically diverse study of people at high risk for developing type 2 diabetes (based on impaired glucose metabolism). There has been high retention of the DPP volunteers in both the clinical trial phase and the outcomes study phase. The collection of health and biological information obtained from the DPP volunteers is an invaluable diabetes research resource that is still being analyzed to understand development of this disease and its complications in people at high risk.

Significance: How is this research relevant to older persons, populations and/or an aging society?

The risk of developing type 2 diabetes increases dramatically with age. According to recent estimates by the Centers for Disease Control and Prevention, diabetes affects over 23.6 million Americans, approximately 90-95 percent of which is type 2 diabetes, and in the 60 and over age group, about 12.2 million, or 23.1 percent, have diabetes. Approximately 57 million more adults are at risk for developing diabetes. In 1988–1994, among U.S. adults aged 40–74 years, 40.1 percent had prediabetes (impaired glucose metabolism). In 2003–2006, 35.4 percent of adults aged 60 years or older had impaired fasting glucose (one form of pre-diabetes). Moreover, it was recently estimated that costs of diabetes in 2007 were \$174 billion, including direct medical costs of \$116 billion. After adjusting for population age and sex differences, average medical expenditures among people with diagnosed diabetes were 2.3 times higher than what expenditures would be in the absence of diabetes. According to the analysis, over half (56 percent) of all health care expenditures attributed to diabetes are for health resources used by the population age 65 years or older, much of which is borne by the Medicare program (Diabetes Care 31:1–20, 2008).

Diabetes is the leading cause of kidney failure and new onset blindness in adults. Heart disease and stroke together are the leading cause of death in people with diabetes. The DPP results showed that type 2 diabetes could be prevented or delayed in people at high risk, including older people. Through its “Small Steps. Big Rewards. Prevent Type 2 Diabetes” campaign, the National Diabetes Education Program has turned the DPP results into a message of diabetes prevention tailored to different populations in the United States., including older Americans, in order to help decrease the burden of type 2 diabetes and its health complications on our society.

Effectiveness: What is the impact and/or application of this research to older persons?

Older Americans at risk of type 2 diabetes now have evidence-based information and tools that can enable them to take steps to prevent or delay this disease and its complications.

Innovativeness: Why is this exciting or newsworthy?

This work was the first evidence that type 2 diabetes could be prevented in an ethnically and racially diverse population at high risk. The interventions tested were effective for people of all ages, particularly older Americans. Analyses of health and biological information collected from the DPP participants during the clinical trial have continued to reveal new information about diabetes development and risk factors. The DPPOS should provide new insights into the sustainability of the DPP interventions and their long-term effects on diabetes health complications.