

## U.S. DIABETES PREVENTION PROGRAM STUDY AND DIABETES PREVENTION PROGRAM OUTCOMES STUDY

The U.S. Diabetes Prevention Program (DPP) study was initiated in 1996 as a randomized controlled clinical trial with the objective of determining whether lifestyle intervention or pharmacotherapy would prevent or delay the progression to type 2 diabetes in adults at high risk of developing the disease. The follow-up study, the Diabetes Prevention Program Outcomes Study (DPPOS), was initiated in 2002 to measure the long-term effects of interventions used in the DPP study on the development of type 2 diabetes and associated complications. The participants of the DPPOS included 88 percent of eligible DPP participants.

For more information on the original DPP study and DPPOS, visit the National Institute of Diabetes and Digestive and Kidney Diseases website:

<https://www.niddk.nih.gov/news/for-reporters/diabetes-prevention-program-outcomes-study/>



### U.S. Diabetes Prevention Program Study<sup>1</sup>

A NIH-funded randomized, controlled clinical trial that compared the effectiveness of a lifestyle intervention program versus pharmacotherapy in the prevention or delay of progression to type 2 diabetes

- Multi-center study of 3,234 adults with prediabetes
  - Forty-five percent of study participants were members of a minority group (African American, Hispanic, Asian, Pacific Islander and American Indian)
  - Study participants also included those over the age of 60, women with a history of gestational diabetes and adults with a first-degree relative with diabetes
- Participants received one of three interventions
  - Individual structured intensive behavioral counseling with the goal of lowering body weight by 7 percent through a low-fat diet and increased physical activity
  - Pharmacotherapy with metformin twice daily plus standard advice on diet and exercise
  - Placebo pills plus standard advice on diet and exercise
- At an average follow-up of three years, the structured intensive behavioral counseling intervention reduced the incidence of diabetes by 58 percent compared with placebo
  - Effects were similar in men and women and in all racial and ethnic groups
  - Among adults 60 years and older, the incidence reduction was even greater at 71 percent
  - Pharmacotherapy with metformin reduced the incidence of diabetes by 31 percent compared to placebo during the same time frame
  - Translates to approximately one case of diabetes prevented per seven persons treated for three years with the lifestyle change intervention
- Estimated cumulative incidence of diabetes at three years was 28.9 percent, 21.7 percent, and 14.4 percent in the placebo, metformin and lifestyle intervention groups

## Ten-year follow-up: Diabetes incidence during the Diabetes Prevention Program Outcomes Study<sup>2</sup>

A follow-up study of the DPP population to compare the effectiveness of DPP interventions in the long-term persistence of reduced diabetes incidence

- All three treatment groups from the original DPP study (lifestyle intervention, metformin, placebo) were offered group-implemented lifestyle intervention; participants in the placebo and metformin groups were subsequently unmasked to their treatment assignment and placebo was stopped
- During the 10 years since the original DPP study randomization, diabetes incidence was reduced by 34 percent in the lifestyle intervention group and by 18 percent in the metformin group compared to placebo
  - The cumulative incidence of diabetes remained lowest in the lifestyle intervention group (5.3 cases per 100 person-years) compared to the metformin group (6.4 cases per 100 person-years) and the placebo group (7.8 cases per 100 person-years)

## Fifteen-year follow-up: Long-term effects of interventions for diabetes prevention in the Diabetes Prevention Program Outcomes Study<sup>3</sup>

An intent-to-treat analysis of original DPP participants to assess the long-term benefits of lifestyle intervention versus pharmacotherapy for diabetes prevention and reduction of diabetes-associated microvascular complications

- During DPPOS, the original lifestyle intervention group was offered two group classes yearly for lifestyle reinforcement and the metformin group received unmasked metformin; all groups received quarterly maintenance lifestyle counseling sessions
- At an average follow-up of 15 years after DPP randomization, diabetes incidence was reduced by 27 percent in the lifestyle intervention group and by 18 percent in the metformin group, compared with the placebo group
- While microvascular complications were not reduced in the total cohort with either intervention, lifestyle intervention reduced microvascular disease significantly in women and, compared to metformin and placebo, reduced the prevalence of microvascular complications in Hispanic Americans
- Participants who did not develop diabetes had a 28 percent lower prevalence of microvascular complications compared with those who developed diabetes

## Long-term effects of the Diabetes Prevention Program interventions on cardiovascular risk factors<sup>4</sup>

Long-term follow-up of the DPP population to assess differences in differences in cardiovascular disease risk factors and the use of lipid and blood pressure medications

- After 10 years' follow-up from DPP baseline, major reductions were seen for systolic and diastolic blood pressure, LDL cholesterol and triglycerides in all three treatment groups
- At year five of DPPOS, lipid medication use was significantly different by treatment group and lowest in the lifestyle intervention group (32 percent); blood pressure medication use differed modestly but not significantly by treatment group and was lowest in the lifestyle intervention group (41 percent)

# TRANSLATIONAL RESEARCH

## DEPLOY pilot study: Translating the Diabetes Prevention Program into the community<sup>5</sup>

A pilot intervention trial to test the implementation of a group-based adaptation of the Diabetes Prevention Program model in the community setting

- A matched-pair, group-randomized trial of 92 participants that compared a group-based lifestyle intervention modeled on the Diabetes Prevention Program study intervention and delivered by YMCA wellness instructors to brief counseling alone
- At 12 months, body weight was reduced by approximately 6 percent in intervention participants and 2 percent in controls compared to baseline levels; intervention participant weight loss was comparable to the original DPP study

## **The Montana Cardiovascular Disease and Diabetes Prevention Program: Translating the evidence into the general community setting<sup>6</sup>**

A feasibility study to determine the potential of implementing an adapted, group-based program modeled on the Diabetes Prevention Program lifestyle intervention in the general community

- Three hundred fifty-five adults at high risk for diabetes or cardiovascular disease were enrolled; 83 percent completed the 16-week core lifestyle intervention program
- Seventy percent of participants achieved the physical activity goal of  $\geq 150$  minutes per week
- Ninety-seven percent of participants lost weight, with 67 percent achieving at least 5 percent weight loss and 45 percent achieving the 7 percent weight loss goal

## **PREVENT-DM: Comparing the effectiveness of lifestyle intervention and medication in an urban female population<sup>7</sup>**

A randomized trial to evaluate the real-world comparative effectiveness of diabetes prevention interventions among Hispanic women

- Ninety-two prediabetic Hispanic women in an urban community health center were randomized to receive either an intensive lifestyle intervention adapted from the Diabetes Prevention Program and delivered by community health workers (promotoras), metformin twice daily or routine medical care in a 1:1:1 allocation
- At 12 months, participants in the lifestyle intervention achieved a mean weight loss of 5.0 percent of their initial body weight, compared with 1.1 percent weight loss among metformin participants and a 0.9 percent weight gain in the standard care group
- Fifty percent of participants in the lifestyle intervention group, 14.8 percent in the metformin group, and 7.1 percent in the standard care group achieved 5 percent weight loss

## **Clinical outcomes and program engagement in a digital Diabetes Prevention Program<sup>8</sup>**

A single-arm, non-randomized trial that examined the relationship of program engagement in the first year to clinical outcomes up to three years post baseline in a digital translation of the Diabetes Prevention Program lifestyle intervention

- The Omada Health Program (formerly “Prevent”), is a digital translation of the Diabetes Prevention Program lifestyle intervention accessible via internet-enabled desktop or mobile devices
  - A 16-week core intervention followed by a 36-week ongoing weight maintenance intervention was delivered to 220 socioeconomically diverse patients enrolled in the Omada Health program
- At a year post baseline, participants who had completed nine or more lessons achieved significant weight loss (–4.9 percent weight change) and reduction in A1C (–0.40); at three years post baseline, participants continued to have sustained weight loss (–2.9 percent weight change) and a reduction in A1C (–0.33)
- Analysis of program engagement metrics found that website logins and group participation were significantly associated with weight loss at 16 weeks and one year

## **Systematic review of translational studies based on the original U.S. Diabetes Prevention Program Study or Finnish Diabetes Prevention Study<sup>9</sup>**

A systematic literature review of translational research based on the U.S. Diabetes Prevention Program study or the Finnish Diabetes Prevention study to assess the impact of intensive lifestyle interventions delivered outside of randomized trials

- Nineteen papers reporting 17 studies of moderate to good quality were included; protocols were all based on the U.S. DPP or Finnish DPS study protocols with modifications to reduce the resources required and increase accessibility
- All studies assessed change in body weight and targeted populations with one or more risk factors for type 2 diabetes
  - Weight loss occurred in all but one study
  - In studies with comparators, weight loss was greater in intervention arms than in control arms

## Impact of the YMCA of the USA's Diabetes Prevention Program on Medicare spending and utilization<sup>10</sup>

A retrospective claims analysis to determine whether a diabetes prevention program reduced medical spending and health care resource utilization in the Medicare population

- Analyzed claims data over a two-year period from 3,319 fee-for-service Medicare beneficiaries who participated in the YMCA of the USA's diabetes prevention program and a matched comparison group
- Overall weighted average savings per member per quarter during the first three years of the intervention period was \$278; authors estimated that the return on investment of this program would be \$2.2 per \$1 for the first year and \$3 per \$1 for the three years
- Throughout the entire intervention period, significant decreases in inpatient admissions and emergency department visits were noted for the intervention group in relation to the comparison group

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