

Results of landmark 11-year study on weight loss's effect on heart disease risks published today

24 June 2013

A landmark study investigating the long-term effects of weight loss on the risks of cardiovascular disease among patients with Type 2 diabetes has now concluded, with significant results to be published today in the *New England Journal of Medicine*.

Conducted at the University of Pittsburgh and at clinical facilities throughout the United States, the multicenter clinical trial investigated the effects of an intensive lifestyle intervention program, intended to achieve and maintain weight loss in overweight or obese people with [Type 2 diabetes](#), on rates of cardiovascular disease. Begun in 2001, the trial enrolled more than 5,000 people at 16 clinical centers across the United States and is the longest [intervention study](#) of its type ever undertaken for patients with diabetes.

John Jakicic, chair and professor in the Department of Health and [Physical Activity](#) in Pitt's School of Education and Director of the Physical Activity and Weight Management Research Center, served as principal investigator for the University of Pittsburgh's role in the study. He, along with colleagues throughout the University, is among the researchers comprising the national Look AHEAD (Action for Health in Diabetes) Research Group, which carried out the study and authored the *New England Journal of Medicine* paper.

Among the study's main findings is that weight loss among members of the study's Intensive Lifestyle [Intervention group](#), provided with a program of weight management and increased physical activity, resulted in no difference in heart attacks and strokes when compared with the study's [control group](#), the Diabetes Support and Education group, which was provided with only general health information and social support.

The effect of the intervention program on weight loss, however, was significant: Participants in the intervention group lost 8.7 percent of their initial body weight after one year of the study versus 0.7 percent among the control group's members; the intervention group also maintained a greater weight loss, 6 percent of their initial weight, versus 3.5 percent for the control group, at the study's conclusion.

The Look AHEAD study is the first to achieve such sustained weight loss. A weight loss of 5 percent or more in short-term studies is considered to be clinically significant and has been shown to improve control of blood pressure, blood sugar, cholesterol, and other risk factors. Comparable weight loss can also help prevent the development of Type 2 diabetes in overweight and obese adults.

"While the findings from the Look AHEAD study did not support that engagement in a weight-loss intervention was effective for reducing the onset of cardiovascular disease incidence or mortality, this does not mean that overweight adults with diabetes should not lose weight and become more physically active," said Jakicic. "Rather, there is an overwhelming amount of evidence from this study to date that has shown that weight loss and physical activity were associated with numerous other health benefits.

"These include improving physical function and quality of life, reduction in risk factors such as lipids and blood pressure with less reliance on medication, better diabetes control with less reliance on medication, improved sleep, psychological and emotional health benefits, and many others," Jakicic said. "Thus, adults with diabetes can begin to realize many of these health benefits with even modest reductions in body weight and modest increases in physical activity."

The study sought to determine whether weight loss achieved with a lifestyle program would help individuals with diabetes live longer and develop less cardiovascular disease. While short-term studies had shown that weight loss improved control of blood sugar and mitigated risk factors for heart disease and stroke in overweight and obese individuals with Type 2 diabetes, the longer-term effects of weight loss were not well studied. In particular, it was unknown whether weight loss achieved with a lifestyle intervention alone could reduce the risk of heart disease in people with Type 2 diabetes.

Type 2 is the most common form of diabetes, affecting approximately 25 million Americans over the age of 20. Complications of Type 2 diabetes include heart disease and stroke, high blood pressure, blindness, kidney disease, the nervous system disease known as neuropathy, and amputations. The total cost of Type 2 diabetes in 2012 was estimated to be \$245 billion. This disease, for which there is no cure but which involves ongoing treatment, can be managed with diet, physical activity including regular exercise equal to at least 30 minutes of brisk walking each day, modest weight loss, and a variety of medications. The Look AHEAD study has shown that these lifestyle factors are effective for improving the management of Type 2 diabetes.

Study participants were individuals between 45 and 75 years of age with Type 2 diabetes and a body-mass index of 25 or greater. Sixty percent of the study participants were women, while 37 percent were from ethnic and racial minority groups.

The University of Pittsburgh's General Clinical Research Center and Clinical Translational Research Center served as participating clinical sites, with researchers here recruiting more than 330 participants over a three-year span. Jakicic credited the Division of Endocrinology within the Department of Medicine and the Department of Psychiatry in Pitt's School of Medicine, and the Department of Epidemiology in Pitt's Graduate School of Public Health, with the success of the local clinical trials.

Participants were assigned randomly to the

Intensive Lifestyle Intervention group or the Diabetes Support and Education group. Members of the Intensive Lifestyle Intervention group were enrolled in a weight management program that provided individual and group support for making changes in eating behaviors and engaging in physical activity. The intervention program focused on home-based, functional activities including helping participants balance, climb stairs, and get out of a chair, among other examples. Diabetes Support and Education group members received what Jakicic called "usual care, with some very infrequent support on general health topics that were not related to diet, physical activity, or weight loss."

Participants were required to have their own health care providers manage their diabetes and other conditions. Look AHEAD did not provide medical care, but it did assist participants in finding a health care provider if they did not have one.

The Look AHEAD study was intended to run for 13.5 years, the maximum length of time researchers had determined might be required to see a difference in heart disease between two groups. After 11 years, however, the Look AHEAD Data and Safety Monitoring Board, an independent monitoring board that provides recommendations to the National Institutes of Health, reviewed the data the study had collected and determined that Look AHEAD could reach the definite conclusion that there were no differences in cardiovascular disease rates between the study's two groups.

Speculating on the failure of weight loss to reduce the risk of cardiovascular disease, researchers suggested that even greater [weight loss](#) may be necessary to reduce cardiovascular risk in diabetes patients who are overweight or obese. They also suggested that by providing participants in both groups, and their health care providers, with annual feedback on the participants' blood pressure, lipids, and blood sugar control, the cardiovascular disease risks for all experiment participants may have been reduced at a comparable rate.

The paper is titled "Cardiovascular Effects of Intensive [Lifestyle Intervention](#) in Type 2 [Diabetes](#)." It appeared online in the *New England Journal of*

Medicine today, June 24, 2013. Research conducted at the University of Pittsburgh's General Clinical Research Center and Clinical Translational Research Center was funded by a Clinical and Translational Science Award and a National Institutes of Health grant.

Provided by University of Pittsburgh

APA citation: Results of landmark 11-year study on weight loss's effect on heart disease risks published today (2013, June 24) retrieved 25 June 2019 from <https://medicalxpress.com/news/2013-06-results-landmark-year-weight-loss.html>

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