

## **Pre-diabetic patients respond to self-directed lifestyle interventions, researchers say**

December 10 2012

Efforts to help overweight patients avoid diabetes through lifestyle changes need not rely on intensive, one-on-one focused programs, a new clinical study from the Stanford University School of Medicine and the Palo Alto Medical Foundation Research Institute has found.

The study, to be published Dec. 10 in the <u>Archives of Internal Medicine</u>, opens up a practical way for <u>primary care physicians</u> to help their patients at high risk for developing diabetes.

Researchers have known for 10 years that intensive intervention programs led by lifestyle coaches to encourage weight loss through healthier diet and exercise help reduce type-2 diabetes incidence. The Diabetes Prevention Program clinical research study, the results of which were published in 2002, found this strategy led to a 58 percent decrease in the incidence of type-2 diabetes, a result that surpassed the benefit of drug treatment.

The new study—headed by Jun Ma, MD, PhD, an associate investigator at the research institute and an affiliate member of the Stanford Prevention Research Center—builds off the DPP's strategy but makes full use of online resources and, in one group, a take-home DVD. If implemented, the new interventions could increase the accessibility and reach of existing educational, coach-based diabetes prevention programs, and free up time for primary care doctors, who are often frustrated with high patient loads that prevent them from providing the individualized care these patients need.



"The big issue in diabetes prevention is how to take what clearly worked for DPP—which was very intensive and one-on-one focused—and get it to the point where it could be established as a program in large group practices," said Randall Stafford, MD, PhD, professor of medicine at the Stanford Prevention Research Center and a senior investigator on the study.

Diabetes currently affects 25.8 million people in the United States, or 8.3 percent of the population. The disease is a major cause of heart disease and stroke, and is the leading cause of kidney failure, nontraumatic lower-limb amputation and new cases of blindness among adults. In 2007, diabetes-related medical costs in the United States were estimated at \$174 billion. Effective health interventions that reach a maximum amount of pre-diabetic patients—those at the highest risk for developing diabetes—are urgently needed to curb the burden of the disease.

What the DPP sported in effectiveness, it lacked in its ability to broadly reach patients at the level of primary care. In the new study, Ma and Stafford set out to determine whether restructuring the DPP to take advantage of online connectivity and health monitoring could be achieved without sacrificing the benefits seen in the original program.

Pre-diabetic patients were recruited from Palo Alto Medical Foundation and randomized into three groups: a coach-led group intervention, a selfdirected DVD intervention or usual care. In addition to offering practical ways to start eating healthier foods and exercising more, the curriculum in both the coach-led and DVD-based interventions also focused on the mental and behavioral strategies necessary to make the changes stick. This lifestyle instruction was delivered over a three-month intensive intervention phase.

Following the first three months of intervention, the participants



regularly received encouraging messages to help them follow through with what they had learned in the initial intervention phase. During this 12-month maintenance phase, participants received supportive emails within an electronic health-record system, and monitored their health goals through the publicly available American Heart Association's Heart360 website. The primary outcome tested in the study was a change in body mass index (a calculation based on a person's height and weight), although other factors, including weight loss, waist circumference, blood pressure and blood glucose, were also measured.

The results show that participants responded to both the coach-led and self-directed interventions, although the coach-led group fared slightly better. At the beginning of the study, the participants had an average BMI of 32; a BMI of 30 or more is considered obese. After the 15-month trial, the average drop in BMI was 2.2 for the coach-led group, 1.6 for the self-directed group and 0.9 for the group that received usual care. The average weight loss was 13.9 pounds for the coach-led group, 9.9 pounds for the self-directed group and 5.3 pounds for usual care. Both interventions also led to a dip in waistline circumference as compared to the usual-care group.

Though the study was too small to generate statistically significant findings along gender lines, they turned up a hint of a gender difference: While men responded with equal success to both the coach-led and selfdirected interventions, women responded better to the coach-led approach.

Stafford points out that the suggested differences between genders highlights the need for options when it comes to lifestyle interventions. "It suggests that a one-size-fits-all program isn't necessarily what we need. We need some way to offer people different styles of intervention," said Stafford.



Narrow demographics were a primary limitation of the study. Participants were all from a single clinic in Silicon Valley, and a large majority were white (78 percent), college-educated (97 percent) and earned more than \$75,000 per year (88 percent). Stafford acknowledged the limited demographics of the study, but said he hopes that similar lifestyle interventions will work in more diverse populations. His group is currently conducting a National Institutes of Health-funded study testing the effectiveness of weight-loss interventions in a low-income, Latino population.

If implemented, the approaches—especially the self-directed DVD—could extend the reach and lower the cost of lifestyle intervention programs. In addition to the cost-benefit of the intervention programs themselves, the real savings will come from diabetes prevention. "Diabetes is an expensive disease to treat and its complications are both personally devastating and societally costly," said Stafford. If patients respond to self-directed programs by losing a modest amount of weight, this could be enough to prevent or significantly delay the onset of type-2 diabetes in high-risk populations, ultimately reducing the burden of this chronic disease.

**More information:** Arch Intern Med. Published online December 10, 2012. doi:10.1001/2013/jamainternmed.987

## Provided by Stanford University Medical Center

Citation: Pre-diabetic patients respond to self-directed lifestyle interventions, researchers say (2012, December 10) retrieved 6 May 2024 from <u>https://medicalxpress.com/news/2012-12-pre-diabetic-patients-self-directed-lifestyle-interventions.html</u>

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