

washingtonpost.com

Study Tests Alternatives to Gastric Bypass

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The Associated Press

Wednesday, March 8, 2006; 10:17 PM

BUFFALO, N.Y. -- Volunteers 100 or more pounds overweight will test various combinations of diet, exercise and medication in search of a non-surgical "gold standard" of treatment for the severely obese.

A five-year study commissioned by the region's largest health insurer will enlist 280 people who would be candidates for gastric bypass surgery. Researchers said Tuesday they hope to measure the safety, cost and effectiveness of the more traditional approaches against those of the surgery.

"Gastric bypass surgery ... has come to the fore as the preferred treatment option for severe obesity and an estimated 170,000 patients underwent this surgery in 2005," said Alphonso O'Neil-White, president and chief executive of BlueCross BlueShield of Western New York, which is recruiting study participants from among its members.

O'Neil-White said the insurer sought the \$5 million study by the University at Buffalo after being unable to find a model of treatment for the severely obese, defined as having a body mass index of greater than 40. A BMI of 18.5 to 24.9 is normal, while an adult with a BMI of 30 or more is considered obese, according to the Centers for Disease Control.

"We set out to develop the gold standard, best-practices model of alternative treatment," said O'Neil-White. He said gastric surgery, in which a small pouch is stapled off from the rest of the stomach and connected to the small intestine, cost the American health care system \$4.5 billion last year _ up 1,000 percent from a decade earlier.

Researchers hope the study will provide guidance to doctors treating severely obese patients, who often have high blood pressure, diabetes, heart disease and other health problems.

"Many (patients) have been involved in repeated struggles to lose weight, perhaps jumping from one fad diet or new promising remedy," said Dr. Michael Noe, the study's lead investigator. "The real problem for many of them is not necessarily a lack of motivation but rather responding to misguided messages or bad advice."

Those taking part in the study will be divided into four groups. Two groups will consume 800 calories a day, with most calories coming from a packaged, nutritionally dense powder to be mixed into shakes, soups and other foods. The other groups will consume 1,200 to 1,500 calories a day. Half of the participants will take an FDA-approved appetite suppressant or fat-blocker while the other half receives no medication. All will receive behavioral treatment to learn how to manage their diets, prevent relapses and stay motivated, and all will be encouraged to walk daily, eventually three miles.

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Participants will be closely supervised for three years and monitored for the next year or two to measure whether weight loss has been maintained.

Researchers expect that participants who consume 800 calories a day for 12 weeks and then increase to 1,200 to 1,500 calories a day, while taking medication, will lose 20 percent or more of their body weight, Noe said.

An estimated 300,000 to 400,000 deaths per year are tied to obesity and overweight and the rates are rising, O'Neil-White said.

Surgeon General Richard Carmona last week said America's obesity epidemic will dwarf the threat of terrorism if the nation does not reduce the number of people who are severely overweight. He called obesity "the terror within."

On the Net:

BlueCross BlueShield of Western New York: <http://www.bcbswny.com>

University at Buffalo: <http://www.buffalo.edu>

Centers for Disease Control: <http://www.cdc.gov>

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