

**Embargoed until:**

June 27, 2010, 4:15 p.m. EDT

## **HEALTHY Study Questions & Answers**

### **What is the HEALTHY Study?**

HEALTHY is a 3-year study in 42 middle schools to determine if changes in school food services and physical education classes, along with classroom activities to promote behavior change, lower risk factors for type 2 diabetes in youth at high risk for the disease. Some risk factors for type 2 diabetes are modifiable, such as overweight and obesity, inactivity, high blood pressure, large waist size, and high blood levels of sugar and insulin. Other risk factors are not modifiable, such as family history and race or ethnicity.

The study, involving 4,603 students, began in the fall of 2006 and ended in the spring of 2009. Half of the 42 schools received the intervention, or program; half, which served as comparison schools, did not. For more information about the study's design and objectives, see [www.ncbi.nlm.nih.gov/pmc/articles/PMC2782907](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2782907).

### **What is body mass index (BMI) and why is it important?**

Body mass index (BMI) is a measurement of weight in relation to height. For most people, BMI is a good predictor of health problems linked to excess weight. For adults, a BMI greater than 25 is considered overweight and greater than 30 is obese. For children, however, BMI is compared to typical values for other children of the same age and sex, using growth charts based on data from a time when obesity in the U.S. was not considered a major problem. Children with a BMI between the 85<sup>th</sup> and 94<sup>th</sup> percentile for their age and sex are considered overweight. Children with a BMI at or above the 95<sup>th</sup> percentile for their age and sex are considered obese. However, because of the increasing rates of overweight and obesity among U.S. children since the 1980s, currently about one-third of children are above the 85<sup>th</sup> percentile, rather than the 15 percent at the time the definitions were established.

### **Were students in the HEALTHY Study at risk for type 2 diabetes?**

When students were first measured in 6<sup>th</sup> grade, about half were overweight or obese, with a BMI at or greater than the 85<sup>th</sup> percentile for their age and sex. More than 15 percent had a first-degree relative with diabetes. Measurements of other type 2 diabetes risk factors, including waist size and fasting levels of blood glucose and insulin, confirmed that many children were at risk for type 2 diabetes. Rates of overweight, obesity and type 2 diabetes are higher in minority and low-income populations. In HEALTHY study schools, 54 percent of students were Hispanic, 18 percent were black, and about 75 percent of students came from low-income households, based on eligibility for free or reduced-price school meals.

### **What were the main findings of the HEALTHY Study?**

By the end of the 3-year study, the number of overweight and obese students— those with a BMI at or greater than the 85<sup>th</sup> percentile—had declined by 4 percent in both comparison and program schools. At the beginning of the study, about 50 percent of children were overweight or obese; at the end, about 46 percent were overweight or obese.

When secondary outcomes were examined, however, the study identified some health measurements for which program schools outperformed comparison schools. The percentage of children with waist size above the 90<sup>th</sup> percentile was lower in program schools than in comparison schools. Insulin levels were also lower in the program schools. High insulin levels or a large waist increase the risk of developing type 2 diabetes, independent of body weight. High insulin levels reflect insulin resistance, the first step on the path to type 2 diabetes. BMI z-score was also lower in program schools, meaning that average BMI for participating students fell more in program than in comparison schools. The BMI z-score is a statistical calculation that uses the distribution, or spread, of BMI values to gauge how far away from the average each child falls. These differences in waist size, insulin, and BMI z-score were all statistically significant. A trend toward lower prevalence of obesity in program schools was also found; this trend approached but did not reach statistical significance (p=0.05). Glucose levels were not different between program and comparison schools.

Among children who started out overweight or obese (BMI at or above 85<sup>th</sup> percentile) in the 6<sup>th</sup> grade, children in program schools had 21 percent lower odds of being obese at the end of the study than similar students in comparison schools, a difference that was statistically significant. Therefore, the HEALTHY intervention seemed to have benefits for children who were already overweight or obese in 6<sup>th</sup> grade. In participating schools, 50 percent of students were in this high-risk group.

### **Why did BMI decline in program schools as well as comparison schools?**

The researchers do not know why the prevalence of overweight and obesity declined in both groups of schools by a nearly identical rate. Future analyses of data from the study will try to determine the reasons for the decline in both groups of schools.

Individuals participating in clinical studies often have better health outcomes than people in the general population, even when they do not receive the intervention being studied. Participating in the HEALTHY Study may have encouraged greater awareness of healthy behaviors in students, parents and staff in comparison schools. Parents of all students were given results of health screens, notified of abnormal weight or blood tests, provided health information, and encouraged to follow-up with a health care provider. Also, HEALTHY Study results may have been influenced by increasing awareness about the consequences of obesity nationwide. In the past few years, many school districts have adopted wellness policies, possible evidence of increasing awareness. HEALTHY Study investigators will look at comparison schools to see whether they made healthy changes to the school environment due to increased awareness about the problem of childhood obesity.

Further studies are needed to determine whether overweight and obesity among children are declining nationwide. Recent data have indicated a national leveling off of obesity in youth. A recent study from the Centers for Disease Control and Prevention, published in the Journal of the American Medical Association on Jan. 20, 2010, found that the prevalence of obesity (BMI at or above the 95<sup>th</sup> percentile on growth charts established before the increase in obesity) in U.S. children and adolescents has remained relatively stable at about 17 percent over the past decade. The rate of overweight and obesity together (BMI at or above the 85<sup>th</sup> percentile on these historical growth charts) has also remained stable at about 32 percent in this age group: <http://jama.ama-assn.org/cgi/content/abstract/303/3/242>.

### **Why did the intervention decrease obesity rates more in overweight and obese children than in the entire sample?**

The researchers speculate that overweight and obese children may need more social support to make healthy changes: the school environment may have made healthy behaviors easier for these children. In addition, the initial health screening may have motivated overweight and obese children to make changes.

### **How did food services change in program schools?**

Program schools provided healthier foods and beverages in cafeterias, snack bars, class events, school stores and vending machines. Specific foods and drinks varied. However, program schools were asked to meet five nutritional goals:

- Lower the fat content of foods;
- Increase servings of fruit and vegetables;
- Increase servings of grains or legumes with at least 2 grams of fiber per serving;
- Limit desserts and snacks to 200 calories per serving or package;
- Limit beverages to water, low-fat (1 percent) milk, and 100% fruit juice (6 oz, limited to breakfast).

Members of the HEALTHY team, many of them registered dietitians, met regularly with school food managers to help them implement the goals and to track progress. Free taste test events were regularly conducted at intervention schools to encourage students to pick the new healthy foods. School food service staff also received regular training.

### **How did physical education (PE) activities change in the program schools?**

The HEALTHY study provided physical education lesson plans, equipment, PE teacher training and mentoring, and school-wide events to promote physical activity in intervention schools. Core activities in PE classes included basketball, soccer, and team handball. In addition to core activities, PE teachers chose from a list of elective activities to complete the PE program. Options included badminton, cooperative/adventure games, dance, floor hockey, football, Frisbee, lacrosse, pickleball, softball, swimming, table tennis, tennis, track and field, and volleyball.

Intervention schools were required to have a minimum of 225 minutes of PE class every 10 days throughout the study. The study goal was that students perform moderate-to-vigorous physical activity (MVPA), defined as achieving a heart rate of at least 130 beats per minute, with a target of 150 minutes of MVPA every 10 school days. The HEALTHY study provided at least one PE teacher assistant for each PE class to help schools achieve this goal.

### **Did program schools offer other activities that fostered healthy behavior?**

The study team developed a series of healthy eating and physical activity learning activities supported by classroom activities. Classroom sessions were delivered weekly to increase knowledge, decision-making skills and peer support for healthy changes. Teachers received about four hours of training in the delivery of this curriculum. The behavioral change curriculum included information about activities outside school. The study also used family outreach strategies, including newsletters sent home to inform families about study activities and promote healthy behaviors at home during school breaks. These materials are available to schools and communities nationwide on the HEALTHY study website <http://www.healthystudy.org/>.

**Will the HEALTHY Study continue?**

The study has ended, and no additional information will be gathered from the students. However, additional analyses by the study group are ongoing. HEALTHY data will be made publicly accessible, so independent researchers may analyze the study findings.

**How many children in the United States are overweight or obese?**

More than two-thirds of U.S. adults are overweight or obese. Among youth 2 to 19 years old, 32 percent are overweight or obese and 17 percent are obese, according to the Centers for Disease Control and Prevention (CDC).

**What is type 2 diabetes?**

Type 2 diabetes is a complex metabolic disease marked by high blood sugar. People with this form of diabetes have insulin resistance and a progressive loss of the ability to produce insulin. Insulin is needed so that sugar in the blood, which comes from eating food, can enter the cells of the body and fuel the body's functions. People with type 2 diabetes are at risk for a wide range of complications affecting the eyes, nerves, kidneys, heart and blood vessels. When diabetes develops in childhood, an individual may be more likely to develop complications at an early age, as many complications are related to how long a person has had diabetes. Many people with type 2 diabetes have other metabolic problems, such as high blood pressure and abnormal lipids. More information about type 2 diabetes is available here: <http://diabetes.niddk.nih.gov/DM/pubs/riskfortype2>.

**How many children in the United States have type 2 diabetes and how many are at risk of developing this disease?**

Once seen only in adults, type 2 diabetes has been rising steadily in youth. The SEARCH for Diabetes in Youth Study, funded by the CDC and the NIH in six regions of the country, is examining diabetes rates in youth. According to SEARCH, from 2002 to 2005

- About 3,700 youth from less than one year of age to 19 years old were newly diagnosed with type 2 diabetes annually
- The rate of new type 2 diabetes cases in youth ages 10 to 19 years was 5.3 per 100,000, with higher rates in minority populations.

The CDC estimates that one in three children born in the year 2000 (and one in two children in high-risk racial and ethnic groups) will develop diabetes in their lifetime: <http://jama.ama-assn.org/cgi/content/abstract/290/14/1884>.

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