

# **USANA Clinical Research Bulletin**

## **Reversal of Metabolic Syndrome through a Lifestyle Change Program involving a Low Glycemic Diet and Exercise**

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### **Background**

Type 2 diabetes has risen to epidemic proportions in the United States and other industrialized countries (1,2). Recent research has shown that this disease is highly preventable, and that lifestyle interventions involving changes in diet and physical activity are effective in reversing many of the risk factors and disease processes associated with this condition (3,4,5). Such approaches are thought to be particularly effective in people with Metabolic Syndrome, a pre-diabetic state involving multiple symptoms including over-weight and central obesity, insulin resistance, elevated blood lipids, elevated blood glucose, and high blood pressure (6).

The objective of this clinical trial was to determine whether a 12-week lifestyle modification program, involving low-glycemic functional foods, a low glycemic diet, and modest exercise could reverse many of the symptoms of Metabolic Syndrome in affected people.

### **Methods**

Twenty-five subjects, five males and 20 females, 20-65 years of age, were recruited for the study. To select people at risk for Metabolic Syndrome, men were required to have a waist measurement >40 inches and women had to have a waist measurement >34.5 inches. Moreover, all had to have two or more of the following additional symptoms of Metabolic Syndrome: elevated blood pressure (>130/85 mm Hg), elevated triglycerides (>150 mg/dl), elevated fasting glucose (>110 mg/dL), low HDL cholesterol (<50 mg/dL for females, <40 mg/dL for males).

The lifestyle change program employed in this study was developed by Dr. Ray Strand, a family practice physician in Rapid City, SD. This 12-week, internet-based program was specifically designed to help people reverse insulin resistance through dietary modification and increased exercise. Specifically, during Weeks 1-4 of the program, subjects were instructed to consume one low-glycemic meal replacement shake for breakfast, a second shake for lunch, one low-glycemic nutrition bar as a daily snack, and a normal, but low-glycemic dinner prepared according to instructions provided by Dr. Strand. During Weeks 5-12 of the program, subjects consumed one low-glycemic meal replacement shake per day, one snack bar, and two normal, but low-glycemic meals. In addition, throughout the 12 weeks, subjects took a multivitamin-mineral supplement daily. All meal replacement shakes, snack bars, and nutritional supplements were provided by USANA Health Sciences, Inc., Salt Lake City, UT (7). Subjects were further coached to increase their physical activity and to ultimately exercise at least 45 min

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per day, five days per week, during the last eight weeks of the program.

To determine the impact of the lifestyle program on the subjects' health, measurements of the following parameters were made during Baseline (Week 0), Interim (Week 6), and Final (Week 12) Visits to the study clinic: weight (lbs), height (in), waist circumference (in), blood pressure (mm Hg), blood cholesterol (total, LDL,

HDL; mg/dL), serum triglycerides (mg/dL), plasma glucose (mg/dL), and insulin sensitivity (8).

### **Results**

Twenty-one of the 25 study participants showed good (>80%) compliance with the dietary and exercise recommendations of the program. Four showed relatively poor compliance. Nevertheless, we included data from all subjects in the statistical analyses of results. The attached figures show the changes in average weight, total cholesterol, serum triglycerides, systolic blood pressure, insulin sensitivity, and urinary 8-isoprostanes (a marker of oxidative stress) for the 25 participants. In addition, the following results were observed. The average BMI of participants declined from  $34 \pm 5$  (Baseline) to  $32 \pm 5$  (final). Waist circumference declined from  $41.5 \pm 4.2$  in (Baseline) to  $38.9 \pm 4.4$  in (Final). Diastolic blood pressure declined from  $85 \pm 7$  mm Hg (Baseline) to  $80 \pm 7$  mm Hg (Final). LDL cholesterol dropped from  $134 \pm 23$  mg/dL (Baseline) to  $111 \pm 24$  mg/dL (Final), while HDL cholesterol remained unchanged at  $43 \pm 10$  mg/dL throughout the study.

### **Discussion**

On average, the 12 week lifestyle modification program employed in this study had dramatic impacts on the health of the 25 subjects. On average, subjects lost 13 lbs of body weight per person over the 12 weeks (about 6% initial body weight). Four subjects lost 25 lbs or more. This weight loss was further reflected in significant declines in BMI and waist circumference. Even more dramatic, however, were the changes in cardiovascular and metabolic health. Blood pressure, for example, declined from an average of 131/86 mm Hg (Baseline) to 121/80 mm Hg (Final). Total cholesterol dropped from an average of 206 mg/dL (Baseline) to 176 mg/dL (Final). Most of this decline resulted from a drop in LDL cholesterol from an average of 134 mg/dL (Baseline) to 111 mg/dL (Final). Fasting blood glucose levels declined slightly over the 12 week program from an average of 97 mg/dL (Baseline) to 95 mg/dL (Final). And a standard Index of Insulin Sensitivity based on a Glucose Tolerance Test increased markedly from an average of 0.111 (Baseline) to a value of 0.127 (Final).

All of these changes are consistent with a reversal of Metabolic Syndrome and with significant improvements in cardiovascular and metabolic health. They are further consistent with a dramatic reduction in the risk of type 2 diabetes. Moreover, it is important to note that, most of the changes in the health parameters measured in this study were continuous through the 12 week period, suggesting that as the lifestyle program is extended, further improvements in health status and reductions in disease risk can be expected.

We conclude that the lifestyle change program employed in this study was fully effective. The shifts in dietary habits to include low-glycemic functional foods and low-glycemic meals, and the modest increases in physical activity offer a valuable approach for reversing Metabolic Syndrome and preventing Type 2 diabetes and heart disease in at-risk people.

### **Acknowledgment:**

This study was funded by USANA Health Sciences, Inc. It was conducted in partnership between USANA and Dr. Ray Strand. The protocol for the study was approved by the Western Institutional Review Board.

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### **Graphs**

Results from the clinical trial measuring Reversal of Metabolic Syndrome through a Lifestyle Change Program involving a Low Glycemic Diet and Exercise. Results for the changes in body weight, total cholesterol, serum triglycerides, systolic blood pressure, insulin sensitivity, and urinary 8-isoprostanes are shown in the six graphs below. In all cases, the changes from Baseline to Week 12 are statistically significant at the  $p < 0.05$  level.

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