

# Successful Internet-Based Lifestyle Change Program on Body Weight and Markers of Metabolic Health

Holly R. Wyatt, M.D.,<sup>1</sup> Lorraine G. Ogden, Ph.D.,<sup>1</sup> Kristen S. Cassic, M.A.,<sup>1</sup> Emily A. Hoagland, M.S., R.D.,<sup>1</sup> Toni McKinnon, R.N.,<sup>2</sup> Natalie Eich, B.S.,<sup>2</sup> Vasiliy Chernyshev, B.S.,<sup>2</sup> Tim Wood, Ph.D.,<sup>2</sup> John Cuomo, Ph.D.,<sup>2</sup> and James O. Hill, Ph.D.<sup>1</sup>

<sup>1</sup>Center for Human Nutrition, University of Colorado Denver, Denver, CO

<sup>2</sup>USANA Health Sciences, Inc., Salt Lake City, UT

## Abstract

**Objective:** The objective of this study was to evaluate the effectiveness of an Internet-based 12-Week Healthy for Life Program in supporting weight loss and improvements in metabolic and cardiovascular health among subjects with metabolic syndrome.

**Research methods and procedures:** Sixty subjects with metabolic syndrome were studied before, during, and after a 12-week online lifestyle intervention program that prescribed a low-glycemic diet, nutritional supplementation, and moderate exercise.

**Results:** The intervention produced an average weight loss of 5.5 kg (5.4%). Measures of glycemic control improved significantly during the study. Fasting insulin was reduced by 32.3% and 120-minute insulin during an oral glucose tolerance test was reduced by 43.6%. Insulin sensitivity was increased as evidenced by a reduction in the homeostatic model assessment (HOMA) index (by 31.6%) and an increase in the insulin sensitivity index. There were also significant improvements in triglycerides, total cholesterol, and blood pressure. At the end of the study, 58.5% of the study completers met criteria for the metabolic syndrome compared to 84.9% at baseline ( $p = 0.002$ ).

## Summary:

This study demonstrates that an online lifestyle change program that prescribes a low-glycemic diet, nutritional supplements, and moderate exercise can successfully produce meaningful weight loss, significant improvements in glycemic control, and significant reductions in risk factors for heart disease in individuals with metabolic syndrome.



Holly R. Wyatt,  
M.D.



James O. Hill,  
Ph.D.

## Introduction

High rates of overweight and obesity in the United States<sup>1</sup> suggest that many Americans are at increased risk for several chronic diseases.<sup>2</sup> Most notably, overweight and obesity are often associated with a cluster of risk factors for diabetes and cardiovascular disease. These

factors include a large waist circumference, elevated blood pressure, elevated triglycerides and fasting glucose, low high-density lipoprotein (HDL) cholesterol, and poor insulin sensitivity. Individuals possessing several of these symptoms are now often diagnosed as having metabolic syndrome,<sup>3</sup> a prediabetic state that recent research indicates may be reversible, in large measure through lifestyle change. Given the rising rates of type 2 diabetes, there is an urgent need to develop lifestyle intervention programs for people with metabolic syndrome to prevent the progression of their disease.

Weight loss is an indicated treatment for both obesity and metabolic syndrome. Modest weight loss (5%–10% of initial weight) can improve cardiometabolic risk factors and reduce the risk of developing type 2 diabetes.<sup>4</sup> The challenge lies in designing and providing programs that can effectively help the large numbers of people with metabolic syndrome to achieve modest weight loss. Several approaches are available. In research settings, behavioral group treatment,<sup>5</sup> individual treatment by counselors,<sup>5</sup> meal replacement programs,<sup>5</sup> and pharmaceutical interventions<sup>6</sup> have shown some success. But given the large number of people who are overweight or obese, and/or who have metabolic syndrome, scale-up remains an issue.

The Internet provides one means to easily and inexpensively deliver weight loss interventions to large numbers of people. That said, success to date in using this tool has been modest.<sup>7</sup> The intent of this trial was to determine whether a 12-week, Internet-based lifestyle modification program prescribing a low-glycemic diet (including low-glycemic functional foods), vitamin and mineral supplements, and modest exercise could reduce body weight and improve symptoms related to the metabolic syndrome and cardiovascular risk.

## Methods and Procedures

### Participants

Male and female subjects with metabolic syndrome (defined as having abdominal adiposity combined with

at least two other risk factors described below) were recruited from the Denver metropolitan area. All subject recruitment and selection was performed by University of Colorado Denver, independently of USANA Health Sciences and The Healthy for Life Program. Eligible subjects were 20 to 60 years of age with a body mass index  $\leq 42$  kg/m<sup>2</sup> and a waist circumference  $> 40$  inches (males) or  $> 35$  inches (females). In addition, subjects had to have at least two of the following measurements at screening and/or baseline: elevated blood pressure (systolic  $> 130$  mm Hg and/or diastolic  $> 85$  mm Hg); elevated triglycerides ( $> 150$  mg/dL); elevated fasting glucose ( $> 100$  mg/dL); or low HDL cholesterol ( $< 40$  mg/dL for males,  $< 50$  mg/dL for females). Participants also had to have access to e-mail and be willing to make changes to their diet and increase their activity level. Participants were excluded if they were pregnant or lactating, had been diagnosed with type 2 diabetes or were taking medication for blood glucose control. Subjects on lipid-lowering medications, with allergies, or significant intolerance to soy foods or with acute or chronic illnesses that prevented participation in the study were also excluded.

All participants provided informed written consent. The study protocol was approved by the Western Institutional Review Board (WIRB). Recruitment was via newspaper and email advertising; a telephone number was provided for subjects to obtain more information and participate in a prescreening interview. Research staff prescreened 262 subjects via telephone. Of these, 80 subjects were screened in person, at which time data were obtained on weight, waist circumference, blood pressure, fasting blood lipids, and fasting blood glucose. There were 20 screen failures, and 60 subjects were enrolled (24 males, 36 females).

### Study Design

Enrolled subjects were asked to participate in a 12-week Healthy for Life Internet program that prescribed a low-glycemic diet and modest exercise. They were provided

**Table 1. Study Design for Nutritional Products and Coaching**

	WEEKS 1–4	Weeks 5–12
Lifestyle Coaching	Subjects received daily/weekly emails and kept an online log of food intake and physical activity	
Supplements (A.M.)	2 USANA Mega Antioxidant pills & 2 USANA Chelated Mineral pills	
Breakfast	1 USANA Nutrimeal™ Shake	1 USANA Nutrimeal™ Shake
Snack	1 USANA Nutrition Bar	1 USANA Nutrition Bar
Lunch	1 USANA Nutrimeal™ Shake	low-glycemic meal
Snack	1 USANA Nutrition Bar	healthy snack
Dinner	low-glycemic meal	low-glycemic meal
Supplements (P.M.)	2 USANA Mega Antioxidant pills & 2 USANA Chelated Mineral pills	

with vitamin and mineral supplements, low-glycemic meal replacement shakes, and nutrition bars as part of the prescribed diet (Table 1). Moreover, they were asked to keep an online food and physical activity diary for the duration of the study.

The following measurements were obtained at baseline, week 6, and week 12: weight, waist circumference, blood pressure, and fasting blood measures of glucose, insulin, hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>), serum triglycerides, total cholesterol, low-density lipoprotein (LDL) cholesterol, HDL cholesterol, high-sensitivity C-reactive protein, vitamin E ( $\alpha$  and  $\gamma$ ), plasma-induced isoprostanes, and urinary isoprostanes. In addition, oral glucose tolerance tests were administered at each visit; pre- and post-glucose and insulin were obtained (at 0 minutes and 120 minutes, respectively), and a finger-stick glucose was obtained at 90 minutes. Indexes of homeostatic model assessment (HOMA) and insulin sensitivity were calculated from these results.<sup>8,9</sup> Subjects also completed the Food Craving Inventory<sup>10</sup> at each visit. All data collection was performed independent of USANA Health Sciences by University of Colorado Denver staff.

## Internet-based lifestyle change program

The 12-week program was developed by a family practice physician, and it was administered over the Internet. The Internet-based behavior modification program served two purposes: (1) to educate participants about the principles and practices of healthy lifestyle change and (2) to help hold participants accountable for adhering to the recommended interventions.

Participants received daily motivational and instructional e-mails that provided guidance in making healthy food choices and increasing physical activity. Participants were also asked to make daily entries in their own online lifestyle journals, recording what they ate, how they exercised, and whether they took their nutritional supplements. Lifestyle journals were reviewed weekly by a lifestyle coach who was then able to offer feedback and personalized guidance concerning program adherence. The coach was also available via e-mail to answer participants' questions regarding the program. In addition, each participant received a copy of the book *Healthy for Life*, which described the lifestyle program and the principles of a low-glycemic diet in greater detail.<sup>11</sup>

### *Low-glycemic diet*

During the 12-week intervention period, subjects were instructed to avoid high-glycemic foods that cause rapid

rises in blood glucose, and instead to eat low-glycemic foods that cause modest but sustained increases in blood glucose. During the first 4 weeks, subjects were instructed to consume one low-glycemic meal replacement shake for breakfast, another for lunch, two low-glycemic nutrition bars as snacks, and a low-glycemic dinner prepared according to instructions provided by the website.

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During the final 8 weeks of the study, subjects were instructed to consume one meal replacement shake for either breakfast or lunch, and two low-glycemic meals again prepared according to instructions. They were also told to consume two low-glycemic snacks per day during this period; one nutrition bar and one snack of their choice. Throughout the study, subjects were told to take the prescribed vitamin/mineral supplements daily. The commercially available supplements, shakes and bars were provided free of charge to the participants by USANA Health Sciences, the study sponsor. The products are outlined in Table 1. Study participants also received \$50 per study visit for a total of \$200 compensation for participation in the study.

### *Statistical methods*

Demographic and baseline characteristics are reported as mean  $\pm$  standard deviation (SD) for continuous variables or number and percentage of participants for categorical variables. To examine changes in outcome measures over time (baseline, 6 weeks, and 12 weeks) primary analyses utilized repeated measures mixed models performed using the SAS PROC MIXED procedure. The repeated measures mixed model includes all available data for each participant and accounts for missing data in the model. An unstructured covariance (type = UN) was specified for the covariance structure and restricted maximum likelihood (REML) estimation was used. Several outcome measures were log-transformed prior to analysis to better approximate a Gaussian distribution and to

reduce the impact of outliers on the analysis. Results for these outcome measures were back-transformed and are thus interpreted on the multiplicative scale (*i.e.*, percent change). All analyses were performed using SAS statistical software (SAS Institute Inc., Cary, NC).

## Results

### Baseline characteristics

Two hundred sixty-two subjects were phone screened for this study and 80 were consented. There were 20 consented screen failures; 60 subjects (24 males, 36 females) were enrolled in the study.

Demographic and screening characteristics for enrolled participants are presented in Table 2 for the overall sample and by gender. Data are presented as mean  $\pm$  SD for continuous variables or number and percentage of participants for categorical variables. -

	MALES n = 24	FEMALES n = 36	TOTAL n = 60
Age (yrs)	51.1 $\pm$ 8.3	53.2 $\pm$ 6.0	52.4 $\pm$ 7.0
Race/ethnicity			
White	19 (79.2%)	26 (72.2%)	45 (75.0%)
Latino/Hispanic	5 (20.8%)	7 (19.4%)	12 (20.0%)
Other	0 (0.0%)	3 (8.3%)	3 (5.0%)
Weight (pounds)	245.6 $\pm$ 37.5	207.0 $\pm$ 31.4	222.5 $\pm$ 38.7
BMI (kg/m <sup>2</sup> )	34.4 $\pm$ 4.6	34.6 $\pm$ 3.9	34.5 $\pm$ 4.2
Waist circumference (in)	46.1 $\pm$ 3.8	43.4 $\pm$ 4.2	44.5 $\pm$ 4.2
SBP (mm Hg)	138.0 $\pm$ 10.6	131.2 $\pm$ 16.2	133.9 $\pm$ 14.5
DBP (mm Hg)	92.9 $\pm$ 6.9	92.8 $\pm$ 9.2	92.8 $\pm$ 8.3
Fasting glucose (mg/dL)	101.2 $\pm$ 16.2	101.0 $\pm$ 13.8	101.1 $\pm$ 14.7
Triglycerides (mg/dL)	232.1 $\pm$ 128.6	210.5 $\pm$ 117.7	219.2 $\pm$ 121.5
LDL cholesterol (mg/dL)	141.1 $\pm$ 24.8	127.7 $\pm$ 32.1	132.9 $\pm$ 30.0
HDL cholesterol (mg/dL)	39.7 $\pm$ 10.8	44.0 $\pm$ 7.4	42.3 $\pm$ 9.1
Data presented as mean $\pm$ standard deviation (SD) or number of participants (% of participants). SBP, systolic blood pressure; DBP, diastolic blood pressure; LDL, low-density lipoprotein; HDL, high-density lipoprotein.			

At baseline 84.9% enrolled subjects met criteria for the metabolic syndrome, 80% had an elevated blood pressure (> 130/85 mm Hg), 65% had triglycerides >150 mg/dL, 33% had a blood glucose > 100 mg/dL, and 68% had low HDL based on gender.

### Attrition

Of the 60 enrolled subjects, 53 (23 males, 30 females) completed the study (88%) and 7 discontinued from the study early. Of the 7 early terminations, 5 subjects withdrew consent and 2 subjects withdrew because of illness.

### Weight and waist circumference change

Over 12 weeks, study participants lost an average of 12.1 pounds (95% confidence interval [CI]: -14.2 to -9.9 pounds  $p < 0.001$ ). This equates to an average 5.4% weight loss (95% CI: -6.4% to -4.4%). Table 3 presents

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changes in body weight during the 12-week program. As shown, the majority of the weight loss (-9.1 pounds, 95% CI: -10.5 to -7.7 pounds,  $p < 0.001$ ) occurred during the first 6 weeks of the program. On average, there was an additional 3.0 pound weight loss during the second 6 weeks (95% CI: -4.1 to -1.9 lbs,  $p < 0.001$ ). There were also significant reductions in BMI (-1.9 kg/m<sup>2</sup>, 95% CI -2.2 to -1.6 kg/m<sup>2</sup>,  $p < 0.001$ ) and waist circumference (-2.0 inches, 95% CI -2.2 to -1.6 inches,  $p < 0.001$ ) during the 12-week program.

VARIABLE	BASELINE	6 WEEKS	12 WEEKS	6-WEEK CHANGE	12-WEEK CHANGE
Weight (lbs)	222.53	213.46	210.47	-9.07 <sup>a</sup>	-12.06 <sup>a</sup>
Percent Weight Loss (%)				-4.1%	-5.4%
Waist Circumference (in)	44.61	43.27	42.58	-1.34 <sup>a</sup>	-2.02 <sup>a</sup>
Mixed model estimates (95% confidence interval [CI]). <sup>a</sup> $p < 0.001$ .					

### Changes in glyceemic control

Measures of glyceemic control improved significantly during the 12-week intervention. Table 4 summarizes these changes. At the end of 12 weeks, fasting insulin was reduced on average by 32.3% (95% CI: -41.1% to -22.2%,  $p < 0.001$ ) and 120-minute oral glucose tolerance test (OGTT) insulin by an average of 43.6% (95% CI: -54.8% to -29.8%,  $p < 0.001$ ). There were no significant changes in fasting glucose ( $p = 0.345$ ), 90-minute OGTT glucose ( $p = 0.067$ ) or 120-minute OGTT glucose ( $p = 0.119$ ). HOMA index was reduced by an average of 31.6% (95% CI: -41.0% to -20.8%,  $p < 0.001$ ) and the insulin sensitivity index (ISI) increased an average of 0.03 points (95% CI: 0.02 to 0.04,  $p < 0.001$ ). At the end of the 12-week intervention, HbA<sub>1c</sub> levels were 1.8% lower than baseline (95% CI: -3.4% to -0.2%,  $p < 0.001$ ). This was the result of a large reduction in HbA<sub>1c</sub> during the first 6 weeks of the program (-2.8%, 95% CI: -4.3% to -1.3%,  $p = 0.001$ ) followed by a 1.1% increase (95% CI: 0.1% to 1.9%,  $p = 0.029$ ; data not shown) during the second 6-week period.

**Table 4. Changes in Glyceemic Control, All Available Data (n = 60): Mixed Model Estimates (95% CI)**

VARIABLE	6-WEEK CHANGE	12-WEEK CHANGE
Fasting glucose, mg/dL	0.10% (-2.78%, 3.07%) $p = 0.947$	1.29% (-1.40%, 4.06%) $p = 0.345$
Fasting insulin, $\mu$ U/mL	-20.92% (-29.27%, -11.59%) $p < 0.001$	-32.33% (-41.11%, -22.23%) $p < 0.001$
HOMA Index	-20.97% (-30.46%, -10.19%) $p < 0.001$	-31.62% (-40.95%, -20.82%) $p < 0.001$
OGTT glucose, mg/dL 90 minutes	-5.31% (-10.35%, 0.00%) $p = 0.050$	-4.94% (-9.96%, 0.38%) $p = 0.067$
OGTT glucose, mg/dL 120 minutes	-13.92% (-22.40%, -4.51%) $p = 0.005$	-7.74% (-16.68%, 2.16%) $p = 0.119$
OGTT insulin, $\mu$ U/mL 120 minutes	-39.49% (-49.76%, -27.13%) $p < 0.001$	-43.64% (-54.77%, -29.77%) $p < 0.001$
HbA <sub>1c</sub> , %	-2.82% (-4.34%, -1.27%) $p < 0.001$	-1.84% (-3.41%, -0.24%) $p = 0.025$

Mixed model estimates of % change in outcome measures (all variables were log transformed prior to analysis and parameter estimates were back transformed after analysis to be interpreted as % change). CI, confidence interval; HOMA, homeostatic model assessment; OGTT, oral glucose tolerance test; HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>.

### Changes in cardiovascular health and inflammation

Table 5 presents the changes in measures of cardiovascular health and markers of inflammation that occurred during the 12-week program. There were significant improvements in all measures at the end of 6 weeks, but by the end of 12 weeks, significant changes were only observed for triglycerides, total cholesterol, and systolic and diastolic blood pressure.

Changes in antioxidants and inflammatory markers were also measured. C-reactive protein levels declined by an average of 26.5% during the 12-week intervention (95% CI: -38.2% to -12.7%,  $p < 0.001$ ). Vitamin E ( $\alpha$ -tocopherol) levels increased by an average of 30.4% (95% CI: 21.2% to 40.4%,  $p < 0.001$ ). Plasma antioxidant reserve<sup>12</sup> was increased 20.4% as measured by a 20.4% reduction in induced isopros-

**Table 5. Changes in Measures of Cardiovascular Health, Antioxidants and Inflammatory Markers All Available Data (n = 60): Mixed Model Estimates (95% CI)**

VARIABLE	6-WEEK CHANGE	12-WEEK CHANGE
Triglycerides, mg/dL <sup>a</sup>	-17.19% (-25.25%, -8.37%) $p < 0.001$	-15.67% (-23.73%, -6.76%) $p = 0.001$
Total Cholesterol, mg/dL	-17.99 (-25.53, -10.46) $p < 0.001$	-10.35 (-17.17, -3.53) $p = 0.004$
LDL Cholesterol, mg/dL	-9.81 (-16.41, -3.22) $p = 0.004$	-5.25 (-11.85, 1.34) $p = 0.116$
HDL Cholesterol, mg/dL	-1.77 (-3.47, -0.06) $p = 0.043$	0.25 (-1.20, 1.71) $p = 0.729$
Systolic Blood Pressure, mm Hg	-6.51 (-10.27, -2.75) $p = 0.001$	-7.88 (-11.82, -3.95) $p < 0.001$
Diastolic Blood Pressure, mm Hg	-5.69 (-8.14, -3.23) $p < 0.001$	-6.76 (-9.09, -4.43) $p < 0.001$
C-reactive protein, mg/dL <sup>a</sup>	-21.26% (-33.08%, -7.34%) $p = 0.005$	-26.53% (-38.19%, -12.67%) $p < 0.001$
Induced Isoprostanes, pg/mL <sup>a</sup>	-18.65% (-24.88%, -11.90%) $p < 0.001$	-20.44% (-26.70%, -13.65%) $p < 0.001$
Urinary Isoprostanes, ng/mg cr <sup>a</sup>	-17.15% (-28.51%, -4.00%) $p = 0.013$	-28.96% (-39.16%, -17.04%) $p < 0.001$

<sup>a</sup>Log-transformed variable.

Mixed model estimates of absolute change in outcome measures (backtransformed to % change for log-transformed variables).

tanases (95% CI: -26.7% to -13.7%,  $p < 0.001$ ) and urinary isoprostanes fell by 29.0% (95% CI: -39.2% to -17.0%  $p < 0.001$ ).

### Changes in food cravings

Table 6 presents changes in scores on the Food Cravings Inventory (FCI) during the 12-week study. Both FCI total scores as well as scores on each of the four subscales were reduced significantly during the 12-week intervention.

### Percentage of completers with metabolic syndrome measurements

Figure 1 illustrates the changes over the course of the study in percentages of completers for each of the metabolic syndrome criteria and prevalence of the metabolic syndrome. At baseline, 84.9% of study completers had three or more criteria defining the metabolic syndrome and at 12 weeks, 58.5% had three or more criteria. The percentage of completers with elevated triglycerides at baseline was 60.4%. This percentage decreased significantly to 45.3% at week 12. In addition, the percentage of completers meeting the criteria for elevated blood pressure (>130/85 mm Hg) decreased from 79.3% at baseline to 43.4% at 12 weeks. Significant changes in the percentage of completers were not noted in the criteria for elevated waist circumference, fasting glucose, or low HDL.

Identical analyses were also performed for the 53 complete cases (participants who attended all three study visits: baseline, 6 weeks, and 12 weeks) and the results were similar to those reported using all available data.

## Discussion

These results demonstrate that an Internet-based lifestyle change program can successfully produce meaningful weight loss in obese individuals with metabolic syndrome. The average weight loss was 5.4% and was associated with clear improvements in glycemic control and reductions in cardiometabolic risk factors.

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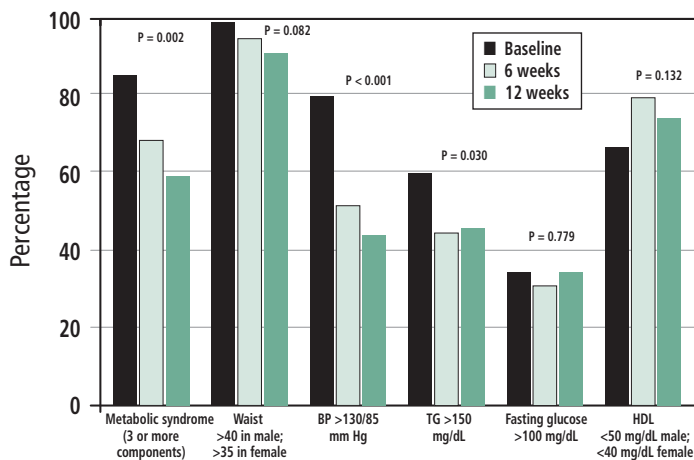
Enrolled subjects were asked to participate in a 12-week Healthy for Life Internet program that prescribed a low-glycemic diet and modest exercise.

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The 12-week Healthy for Life program was delivered via the Internet but involved using standard weight loss tools such as meal replacements, self-monitoring, behavioral change strategies, and low-glycemic diets. The results are significant in that they show the feasibility of using standard tools delivered via an Internet format to achieve weight loss in obese individuals with metabolic syndrome. Given the need for strategies to help large numbers of obese individuals achieve weight loss, this is significant.

**Table 6. Changes in Food Craving Inventory (FCI) Scores, All Available Data (n = 60): Mixed Model Estimates (95% CI)**

VARIABLE	BASELINE	6 WEEKS	12 WEEKS	6-WEEK CHANGE	12-WEEK CHANGE
FCI total score (average)	2.47 (2.35, 2.59)	1.81 (1.67, 1.96)	1.71 (1.60, 1.82)	-0.66 (-0.81, -0.51) $p < 0.001$	-0.76 (-0.89, -0.63) $p < 0.001$
FCI Subscales:					
High fat	2.15 (1.99, 2.31)	1.77 (1.62, 1.92)	1.69 (1.56, 1.82)	-0.38 (-0.53, -0.23) $p < 0.001$	-0.46 (-0.61, -0.31) $p < 0.001$
Sweets	2.64 (2.44, 2.85)	1.66 (1.48, 1.84)	1.66 (1.49, 1.83)	-0.99 (-1.19, -0.78) $p < 0.001$	-0.99 (-1.18, -0.79) $p < 0.001$
Carbohydrate/starches	2.53 (2.37, 2.70)	1.93 (1.76, 2.11)	1.70 (1.57, 1.83)	-0.60 (-0.80, -0.41) $p < 0.001$	-0.83 (-1.01, -0.66) $p < 0.001$
Fast food fats	2.71 (2.54, 2.89)	2.08 (1.91, 2.26)	1.98 (1.83, 2.12)	-0.63 (-0.81, -0.45) $p < 0.001$	-0.74 (-0.91, -0.57) $p < 0.001$



**Figure 1. Percentage of completers with metabolic syndrome and metabolic syndrome criteria.**

Weight loss was not the only end point measured in this trial. On average, the 53 subjects who completed the study experienced improvements in many of the metabolic and cardiovascular risk factors that were studied. Moreover, by the end of the study, the number of subjects who met the criteria for metabolic syndrome had dropped by one third, adding more support to the clinical significance of lifestyle modification in promoting overall health.

A weakness of the present study was the absence of a no-treatment control group. However, given the natural course of development of chronic disease, we think it is unlikely that a no-treatment control group would have shown similar improvements. It will be important to continue to evaluate this online program and to compare it to a control group in the future. It will also be important to evaluate the long-term sustainability of the intervention. However, given the urgent need to develop effective interventions that can easily be delivered to large numbers of people with metabolic syndrome, these results are promising.

#### *Availability of programs and tools utilized in this research study*

The nutritional supplements (the USANA Essentials™) meal replacement shakes and snack bars used in this study were provided by USANA Health Sciences, Inc. (Table 1). To learn more about USANA's products, visit [www.usana.com](http://www.usana.com). Products can be ordered online or by calling a customer service representative at 888-950-9595. The 12-week Healthy for Life program used in this clinical trial is available at [www.releasingfat.com/](http://www.releasingfat.com/).

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## Author Disclosure Statement

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