

# The Effects of a Commercially Available Weight Loss Program Among Obese Patients with Type 2 Diabetes: A Randomized Study

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**Abstract:** The purpose of this study was to assess the effects of a commercially available weight loss program on weight and glycemic control among obese patients with type 2 diabetes. Participants included 69 patients (49 females, 20 males) with type 2 diabetes who had a mean  $\pm$  SD age of  $52.2 \pm 9.5$  years, a body mass index of  $39.0 \pm 6.2$  kg/m<sup>2</sup>, and hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) of  $7.5 \pm 1.6\%$ . Over half (52.2%) of the participants were African American. Participants were randomly assigned to: 1) a portion-controlled diet (NutriSystem<sup>®</sup> D<sup>™</sup>) (PCD) or 2) a diabetes support and education (DSE) program. After the initial 3 months, the PCD group continued on the PCD for the remaining 3 months, and the DSE group crossed over to PCD for the remaining 3 months. The primary comparison for this study was at 3 months. At 3 months, the PCD group lost significantly more weight ( $7.1 \pm 4\%$ ) than the DSE group ( $0.4 \pm 2.3\%$ ) ( $P < 0.0001$ ). From 3 to 6 months the change in weight for both groups was statistically significant. After 3 months, the PCD group had greater reductions in HbA<sub>1c</sub> than the DSE group ( $-0.88 \pm 1.1$  vs  $0.03 \pm 1.09$ ;  $P < 0.001$ ). From 3 to 6 months the PCD group had no further change in HbA<sub>1c</sub>, while the DSE group showed a significant reduction. These data suggest that obese patients with type 2 diabetes will experience significant improvements in weight, glycemic control, and cardiovascular disease risk factors after the use of a commercially available weight management program.

**Keywords:** obesity; type 2 diabetes; commercial weight loss program; portion control

## Introduction

It is clear that obesity increases the risk for developing diabetes in both men and women. Having a body mass index (BMI) of 30 kg/m<sup>2</sup>, for example, increases the relative risk of having type 2 diabetes by 12% in men<sup>1</sup> and 40% in women.<sup>2</sup> Moreover, moderate weight loss decreases the risk of developing type 2 diabetes by nearly 60%<sup>3,4</sup> and confers significant improvements in glycemic control among those who already have diabetes.<sup>5</sup> Less is known about the effects of commercially available weight loss programs, particularly among those with type 2 diabetes. There have been repeated calls for commercial providers to assess their products and programs in randomized trials.<sup>6,7</sup> Such data are necessary to provide an empirical basis for any claims and to present information to physicians and their patients about the expected effects of commercially available weight control programs.

The purpose of this study was to assess the effects of a commercially available weight loss program on weight and glycemic control among obese patients with type 2 diabetes using a randomized controlled trial design.

## Materials and Methods

### Participants

Participants included 69 obese patients with type 2 diabetes recruited from newspaper advertisements, flyers, and physician referrals. Inclusion criteria were a BMI of 30 to 50 kg/m<sup>2</sup>, age of 21 to 75 years, and a screening hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>)  $\geq$  6. Study applicants were excluded if they had serious medical illnesses, such as uncontrolled hypertension ( $\geq$  180/100 mm Hg), took lipid-lowering medications, were pregnant or lactating, or took medications that may affect body weight. The use of metformin, thiazolidinediones, and sulfonylureas was permitted. The use of any other medications to treat diabetes, including insulin, was an exclusion criterion. Participants were recruited, enrolled, and followed from August 2007 to December 2008. All participants gave written informed consent to take part in the study, which was approved by the Institutional Review Board at Temple University.

Participants were randomly assigned, with the use of a random-number generator, to: 1) a prepackaged, portion-controlled diet plan (PCD) or 2) a diabetes support and education (DSE) program. The primary comparison for this study was at 3 months. The study statistician generated the random allocation sequence and the research coordinator enrolled participants and randomly assigned them to condition. After the initial 3 months, the PCD group continued on the PCD meal plan for an additional 3 months and the DSE group crossed over to a PCD meal plan for the remaining 3 months.

### Portion-Controlled Diet

Approximately half of the participants (n = 35) were assigned to a treatment consisting of a NutriSystem<sup>®</sup> D™ PCD. Women consumed approximately 1250 calories per day and men consumed approximately 1550 calories per day. Women were instructed to consume 3 meals and 1 snack per day from NutriSystem<sup>®</sup> D™ foods for a total of 690 kcal/day. Women added conventional foods (2 additional sources of dairy, fruit, lean protein, and fat, and 4 sources of vegetables) to their daily meal plan to total approximately 1250 kcal/day. Men added 2 additional sources of dairy, fruits, and lean proteins, 3 sources of fat and carbohydrates, and 4 sources of vegetables to their 3 NutriSystem<sup>®</sup> D™ meals and 2 snacks for a total of approximately 1550 calories per day. The mean  $\pm$  standard deviation (SD) glycemic index (GI) of the NutriSystem<sup>®</sup> D™ foods was  $40.2 \pm 11.0$  with a mean glycemic load (GL) of  $7.2 \pm 3.4$ . The calculated GI and GL for the PCD plan (including the

recommended conventional foods) was  $32.5 \pm 2.3$  and  $55.8 \pm 0.2$  for women and  $34.3 \pm 2.0$  and  $66.6 \pm 0.2$  for men. The NutriSystem<sup>®</sup> D™ foods were an average of 47% carbohydrate, 30% protein, and 23% fat.

The PCD participants received behavioral treatment in groups of 8 to 12 people, led by a health care professional with experience in behavioral weight control. Sessions were weekly from weeks 1 to 12 and biweekly from weeks 13 to 24. Topics included self-monitoring, stimulus control, goal setting, and relapse management.<sup>8</sup> During the first 12 weeks, participants were provided the same 12-week behavioral-support materials that are currently provided in the NutriSystem<sup>®</sup> D™ program.

### Diabetes Support and Education

The remaining participants (n = 34) were assigned to a program of DSE. Participants attended 3 group sessions of 8 to 12 people in weeks 1 to 12 (weeks 1, 5, and 9) consisting of support lessons on diabetes management, physical activity, and nutrition, very similar to those done in the Look AHEAD (Action For Health in Diabetes) study.<sup>5</sup> After 12 weeks of DSE, participants began the same weekly comprehensive group behavioral treatment and the NutriSystem<sup>®</sup> D™ prepackaged, portion-controlled meal plan as did PCD participants in weeks 1 to 12.

Both PCD and DSE participants were prescribed physical activity (principally walking). Beginning at week 4, the PCD group was instructed to participate in 4 sessions of 20 minutes each and progressing by week 24 to 5 sessions of 40 minutes each. Beginning at week 16, the DSE group was instructed to participate in 4 sessions of 20 minutes each and progressing, by week 24, to 4 sessions of 40 minutes each. The following outcomes listed below were assessed at baseline, 3 months, and 6 months.

### Weight and Height

Body weight was measured on calibrated scales (Detecto; Cardinal Scale Manufacturing Company, Webb City, MO) while participants wore light clothing and no shoes. Height was measured by a stadiometer (Harpender; Holtain Limited, Crosswell, UK) at baseline. Height and weight were measured twice and the average of the 2 readings was used to determine baseline height and weight. Body mass index was calculated as weight (kg) divided by height (m<sup>2</sup>).

### Waist Circumference

Waist circumference was measured in centimeters using a standard tape measure (Gulick II; Country Technology, Gays

Mills, WI). Participants remained standing while the upper hip bone and the top of the right iliac crest were palpitated. The measuring tape was placed in a horizontal plane around the abdomen at the level of the iliac crest. Waist circumference was measured twice and the average of the 2 readings was used.

### Blood Pressure

Blood pressure was assessed by using automated instruments (Dinamap ProCare 200; GE Medical Systems, Milwaukee, WI) with cuff sizes based on measured arm circumference. After sitting quietly for 5 minutes, 2 blood pressure readings were taken separated by a 1-minute rest period. The average of the 2 readings was used to determine blood pressure.

### Serum Measures

Hemoglobin A<sub>1c</sub>, glucose, triglycerides, and total cholesterol were measured from samples obtained after participants fasted overnight (12 hours). Samples, other than HbA<sub>1c</sub>, were centrifuged to separate serum. All samples were shipped overnight to a commercial laboratory, where the assays were performed (Quest Diagnostics, Horsham, PA). Details of each assay are described at <http://www.questdiagnostics.com/hcp/qtim/testMenuSearch.do>.

### Quality of Life

The Short Form-36 (SF-36) version was used to measure general health-related quality of life. A total score and 2 summary scores: physical summary (4 domains, 21 items) and mental health summary (4 domains, 14 items) were analyzed.<sup>9</sup>

### Statistical Analyses

Differences between groups at baseline were assessed using independent samples t-tests or Wilcoxon rank-sum tests for continuous variables, as appropriate, and Chi-square tests for categorical variables. The primary assessments were intention-to-treat analyses at 3 months on each outcome using a linear mixed-effects model with time, treatment, and a time by treatment interaction included as explanatory variables. This model posited an unrestricted structure on the variance-covariance matrix of the residuals on all 69 participants. Analysis of covariance, with initial values as covariates, was used as secondary sensitivity analysis on the 68 participants who completed baseline and month 3 assessments. Results from both analyses were similar (same direction and significance). Analyses were conducted on

absolute values but reported as change and/or percentage change for ease of interpretation. In the case of non-normally distributed errors, outcome measures were log-transformed. Six-month data are reported as within-group changes from 3 months using paired t-tests.

## Results

### Participants

Baseline characteristics of the 69 study participants (49 women, 20 men) are listed in Table 1. There were no significant differences between the 2 groups in any baseline variable. Participants had a mean  $\pm$  standard deviation age of  $52.2 \pm 9.5$  years, a BMI of  $39.0 \pm 6.2$  kg/m<sup>2</sup>, and an HbA<sub>1c</sub> of  $7.5 \pm 1.6\%$ . Over half (52%) of the participants were African American and 41% were European American.

### Attrition

Nearly all ( $n = 68$ , 98.6%) of the participants completed 3 months of the study (34 PCD; 34 DSE), and most ( $n = 58$ , 84.1%) completed 6 months (30 PCD, 28 DSE diet). There was no statistically significant difference in attrition between the PCD and DSE groups at 3 (2.9% vs 0%) or 6 months (14.3% vs 17.6%).

### Weight

At 3 months, the PCD group lost significantly more weight than the DSE group ( $P < 0.0001$ ). The PCD group lost  $7.1 \pm 4\%$  of initial weight for an average of  $8.2 \pm 5.2$  kg while the DSE group lost  $0.4\% \pm 2.3\%$  of initial weight for an average of  $0.6 \pm 2.6$  kg. The PCD group also showed significantly greater reductions in BMI and waist circumference than the DSE group at 3 months (Table 2).

The PCD group continued to lose weight from 3 to 6 months (within-group,  $P < 0.01$ ) for a total weight loss of  $9.7 \pm 6.7\%$ . After the DSE group crossed over to receive the PCD treatment, they lost weight from month 3 to 6 (within-group,  $P < 0.0001$ ) for a total weight loss of  $5.3 \pm 3.7\%$ .

### Hemoglobin A<sub>1c</sub>

After 3 months, the PCD group had greater reductions in HbA<sub>1c</sub> than the DSE group ( $-0.88 \pm 1.10$  vs  $0.03 \pm 1.09$ ;  $P = 0.001$ ) (Table 2). The mean value of the PCD group went from 7.6% to 6.7%. Although there were no differences in the percentage of patients in each group who met the American Diabetes Association goal of  $< 7\%$  at baseline ( $P = 0.23$ ), 79% of the PCD participants met the goal compared with 47% of DSE participants after 3 months ( $P < 0.0001$ ). The PCD group's HbA<sub>1c</sub> did not change from

**Table 1.** Baseline Characteristics of Participants

Measures	PCD	DSE	All
Patients (n)	35	34	69
Gender, n (%)			
Male	9 (25.7)	11 (32.2)	20 (29.0)
Female	26 (74.3)	23 (67.7)	49 (71.0)
Race, n (%)			
White	13 (37.1)	15 (44.1)	28 (40.6)
African American	21 (60)	15 (44.1)	36 (52.2)
Asian	0 (0)	0 (0)	0 (0)
Hispanic/Latino	0 (0)	0 (0)	0 (0)
American Indian/Alaska Native	0 (0)	2 (5.9)	2 (2.9)
Other/more than one race	1 (2.9)	2 (5.9)	3 (4.3)
Age (years)	52.1 ± 7.7	52.8 ± 11.2	52.2 ± 9.5
Body mass index (kg/m <sup>2</sup> )	39.1 ± 5.5	38.9 ± 6.9	39.0 ± 6.2
Weight (kg)	111.5 ± 19.3	110.9 ± 23.5	111.2 ± 21.3
Waist circumference (cm)	122.8 ± 15.8	123.3 ± 17.6	123 ± 16.6
Systolic blood pressure (mm Hg)	126 ± 17	124.6 ± 18.9	125.3 ± 17.9
Diastolic blood pressure (mm Hg)	73.6 ± 10.8	73.9 ± 12.3	73.7 ± 11.5
HbA <sub>1c</sub> (%)	7.6 ± 1.6	7.5 ± 1.7	7.5 ± 1.6
Glucose (mg/dL)	149.5 ± 62.8	151.4 ± 68.3	150.4 ± 65.1
Total cholesterol (mg/dL)	191.1 ± 47.1	188.5 ± 33.4	189.8 ± 40.8
Triglycerides (mg/dL)	159.6 ± 88.8	127.7 ± 56	143.9 ± 75.6

**Abbreviations:** DSE, diabetes support and education program; HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>; PCD, portion-controlled diet (NutriSystem®).

Data are means ± or frequency (%).

There were no significant differences between the 2 groups.

3 to 6 months (within-group,  $P = 0.82$ ), for a total 6-month change of  $-0.90 \pm 1.28$ . After the DSE group crossed over to receive the PCD treatment, they reduced HbA<sub>1c</sub> from month 3 to 6 (within-group,  $P < 0.001$ ) for a total change of  $-0.87 \pm 1.6$ .

## Secondary Measures

The PCD group showed greater reductions than the DSE group in systolic blood pressure, triglycerides, and total cholesterol and a similar, but not significant, trend for diastolic blood pressure (Table 2). The PCD group showed significantly greater improvements in quality of life than the DSE group on the physical health and mental health summary scales and on the total score of the SF-36.

## Discussion

When compared with a standard diabetes education and support program, the NutriSystem® D™ program produced a clinically and statistically significant weight loss of 8.2 kg (7.1%). These 3-month weight losses meet those achieved by large diabetes-prevention studies at 6 months of treatment<sup>3,4</sup>

and approximate those achieved by Look AHEAD study at 1 year (8.6%).<sup>5</sup> They also compare favorably to those obtained at a hospital-based program after 34 weeks (6.8%).<sup>10</sup> These weight losses are even more remarkable given that more than half (52%) of the participants were African Americans because African Americans tend to lose less weight than whites across a variety of treatment approaches.<sup>11-14</sup>

The PCD program also produced significant changes in HbA<sub>1c</sub>. The 0.9% reduction in HbA<sub>1c</sub> is impressive and compares favorably with medical management of type 2 diabetes.<sup>15</sup> Not surprisingly, these weight losses were also associated with significant improvements in waist circumference, blood pressure, serum triglycerides, total cholesterol, and quality of life.

These data suggest that obese patients with type 2 diabetes will experience significant improvements in weight, glycemic control, and cardiovascular disease risk factors after 3 months use of a prepackaged, portion-controlled meal plan such as NutriSystem® D™. The clinical success of this approach is likely because of the structured approach of the meal plan. Structure has been shown to help facilitate adherence

**Table 2.** Change in Physical Measures Among Participants at 3 Months (N = 69)

Measure	PCD	DSE	P Value
Patients (n)	34	34	
Weight (kg)			
Baseline	111.5 ± 19.3	110.9 ± 23.5	
3 months	103.9 ± 17.6	110.4 ± 23.0	
Adjusted change	-8.2 (-9.5 to -6.7)	-0.6 (-2.0 to 0.8)	< 0.0001
BMI (kg/m <sup>2</sup> )			
Baseline	39.1 ± 5.5	38.9 ± 6.9	
3 months	36.6 ± 5.4	38.5 ± 6.8	
Adjusted change	-2.6 (-3.3 to -1.9)	-0.4 (-1.1 to 0.3)	< 0.0001
Waist circumference (cm)			
Baseline	122.8 ± 15.8	123.3 ± 17.6	
3 months	115.7 ± 14	123.1 ± 17.2	
Adjusted change	-7.6 (-9.5 to -5.6)	-0.2 (-2.2 to 1.8)	< 0.0001
HbA <sub>1c</sub> (%)			
Baseline	7.6 ± 1.6	7.5 ± 1.7	
3 months	6.7 ± 1.3	7.5 ± 1.8	
Adjusted change	-0.9 (-1.2 to -0.5)	0.03 (-0.3 to 0.4)	0.001
Fasting glucose (mg/dL)			
Baseline	149.5 ± 62.8	151.4 ± 68.3	
3 months	115.2 ± 35.2	144 ± 68.6	
Adjusted change	-35 (-55.2 to -14.8)	-7.4 (-27.6 to 12.9)	0.02*
Systolic blood pressure (mm Hg)			
Baseline	126 ± 17	124.6 ± 18.9	
3 months	121 ± 15.6	128.2 ± 20.9	
Adjusted change	-5.9 (-12.3 to 0.5)	3.6 (-2.7 to 9.8)	0.04*
Diastolic blood pressure (mm Hg)			
Baseline	73.6 ± 10.8	73.9 ± 12.3	
3 months	74 ± 11.4	78.9 ± 8.8	
Change	0 ± 9.2	5.1 ± 11.9	
Adjusted change	0.1 (-3.6 to 3.8)	5.1 (1.4 to 8.7)	0.06
Triglycerides (mg/dL)			
Baseline	159.6 ± 88.8	127.7 ± 55.9	
3 months	116.9 ± 55.6	133.7 ± 64.1	
Adjusted change	-44 (-59.6 to -28.3)	6 (-9.7 to 21.7)	< 0.0001*
Total cholesterol (mg/dL)			
Baseline	191.1 ± 47.1	188.5 ± 33.4	
3 months	170.2 ± 49.4	186.8 ± 39.8	
Adjusted change	-22.3 (-32.2 to -12.5)	-1.8 (-11.7 to 8.2)	0.005
SF-36 total scale			
Baseline	72.2 ± 18.3	75.8 ± 13.7	
3 months	81.1 ± 13.1	74.9 ± 13.7	
Adjusted change	8.5 (4 to 13)	-0.8 (-5.4 to 3.8)	0.005
SF-36 physical health			
Baseline	70.4 ± 21.5	72.6 ± 15.2	
3 months	80 ± 15.8	71.4 ± 17.2	
Adjusted change	8.9 (4.2 to 13.6)	-1.2 (-6 to 3.6)	0.004
SF-36 mental health			
Baseline	74 ± 17.5	79.4 ± 16.8	
3 months	82.1 ± 13.5	78.5 ± 13.9	
Adjusted change	-8 (2.5 to 3.5)	-0.7 (-6.3-4.9)	0.03

**Abbreviations:** BMI, body mass index; DSE, diabetes support and education program; HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>; PCD, portion-controlled diet (NutriSystem®); SD, standard deviation; SF-36, Short Form-36.

Unadjusted baseline and 3-month data are reported as means ± SD.

Adjusted change is reported as means (95% confidence intervals) and were obtained from linear mixed-effects models with time, treatment, and a time by treatment interaction included as explanatory variables.

\*P values were obtained from a linear mixed-effects model on the log-transformed outcome, which were similar in direction and significance to analyses performed on the raw outcome.

and increase weight loss compared with conventional foods.<sup>16,17</sup> Based on data that low GI and GL diets have beneficial effects that are independent of weight change,<sup>18–20</sup> it is possible that the low GI and GL nature of this meal plan conferred independent effects. The current design, however, does not allow us to separate any weight-independent effects on glycemic control.

This study had several strengths, including being one of the few randomized assessments of a commercially available weight control program. In addition, over half of the participants were African American, a group that has a disproportionately high prevalence of obesity. Finally, this study was conducted among obese patients with type 2 diabetes, a group that will clearly benefit from weight control. The study also had some limitations, including relatively short study duration and the inability to separate out the effects of greater professional contact among the PCD group. Given these initial impressive results, future studies should assess the efficacy of this approach beyond a clinical setting and follow patients for a longer time period.

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## Conflict of Interest Statement

Gary D. Foster, PhD and Wayne Satz, MD disclose conflicts of interest with NutriSystem® D™ (consultants). Kelley E. Borradaile, PhD, Stephanie S. Vander Veur, MPH, Kerri Leh Shantz, MPH, Rebecca J. Dilks, RD, Edie M. Goldbacher, PhD, Tracy L. Oliver, PhD, RD, and Caitlin A. LaGrotte, MEd disclose no conflicts of interest. Carol Homko, PhD, RN, discloses a conflict of interest (consultant) with Abbott Diabetes Care.

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