Clinical Research

The scientific literature supports key components of the Nutrisystem® programs, including the use of pre-packaged meals, low-GI foods, remote counseling, and self-monitoring of eating, activity, and progress. In addition to the broad scientific support for elements of the Nutrisystem programs, there is direct evidence in support of the Nutrisystem programs from clinical trials as well as analyses of our customers' outcomes.

Clinical Trials

1. Foster GD et al. The effects of a commercially available weight loss program among obese patients with type 2 diabetes: a randomized study. Postgraduate medicine 2009; 121:113-18.
Click here to view abstract

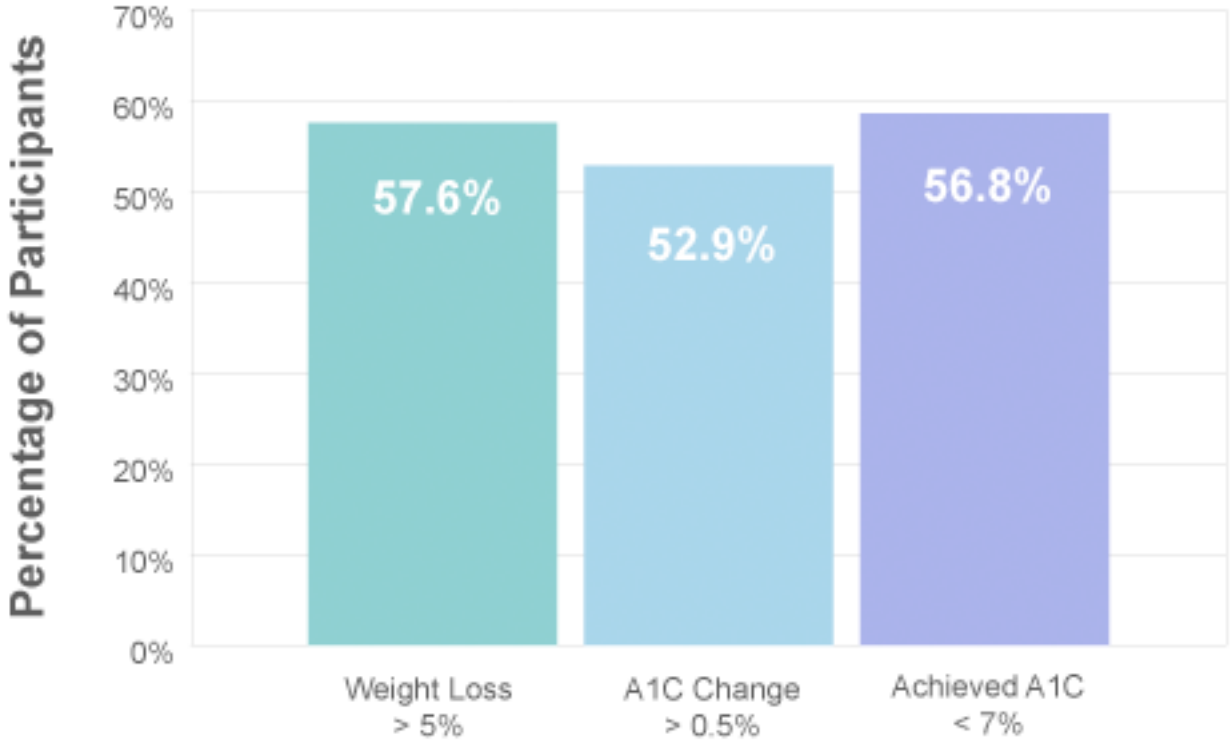
2. Foster GD et al. A randomized comparison of a commercially available portion-controlled weight-loss intervention with a diabetes self-management education program. Nutrition and Diabetes 2013; 3:e63. doi: 10.1038/nutd.2013.3.
Click here to view abstract

These two clinical trials examined the effects of Nutrisystem® D® on weight, hemoglobin A1C, and several additional metabolic outcomes among participants with type 2 diabetes. The 2009 study compared 3 months of Nutrisystem D, in conjunction with counseling sessions, to 3 months of information and support sessions about diabetes management. In months 4-6, all participants received Nutrisystem D. Patients on insulin were excluded from this study. The 2013 study, which included participants on insulin, compared Nutrisystem D, in conjunction with counseling sessions, to structured diabetes self-management education. Both interventions were delivered in 9 sessions over 6 months.

The table below summarizes the mean 6-month changes from baseline among all participants randomized to receive the Nutrisystem D intervention in both trials, separately and combined. These data are from an unpublished secondary analysis of within-group changes observed in the intent-to-treat samples of the two trials. All changes from baseline reported here are statistically significant ($p < 0.05$).

Change Variable	Study 1 (n=35)	Study 2 (n=50)	Combined (n=85)
Weight (% change in initial weight)	- 7.1%	- 7.8%	- 7.5%
Body Mass Index	- 3.1 kg/m^2	- 3.5% kg/m^2	- 3.3 kg/m^2
Waist Circumference	- 3.2 in	- 2.5 in	- 2.8 in
A_{1c}	- 0.8%	- 0.7%	- 0.73%
Total Cholesterol	- 14.2 mg/dl	- 8.6 mg/dl	- 10.9 mg/dl
Triglycerides	- 44 mg/dl	- 26.3 mg/dl	- 33.6 mg/dl

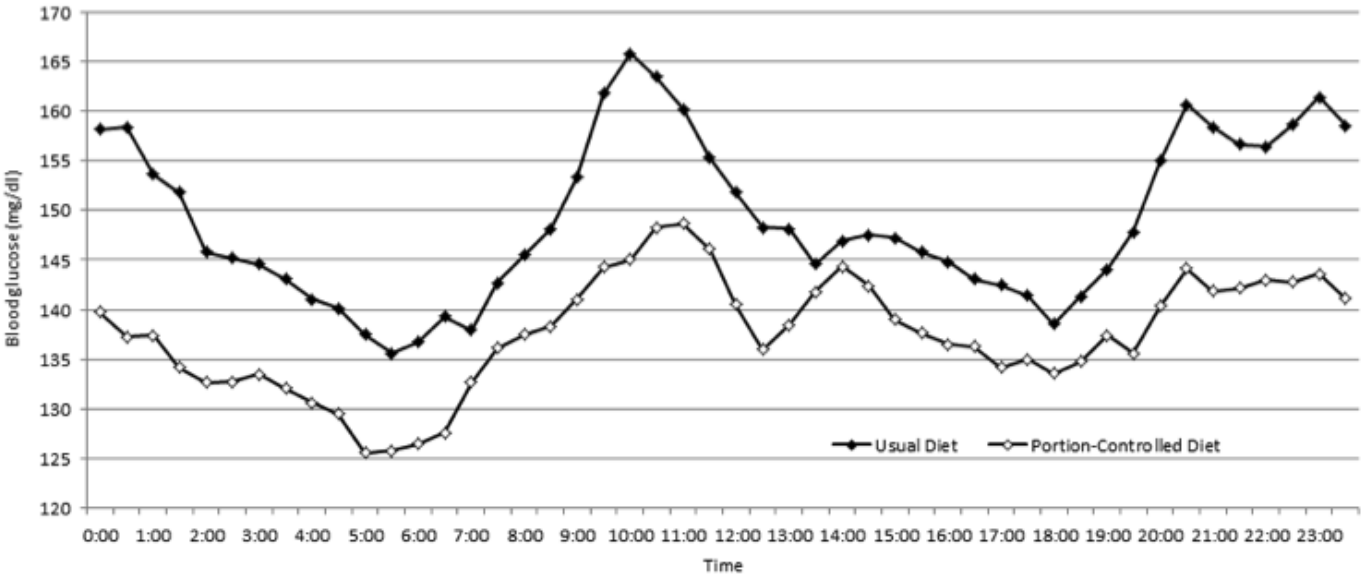
As shown in the figure below, more than half of Nutrisystem D participants in the two studies combined achieved clinically meaningful changes in weight and A1C. Among persons who entered the study with A1C > 7.0%, more than half achieved A1C < 7.0% at 6 months.



These findings suggest both statistically and clinically meaningful reductions in body weight and A1C among participants who received the Nutrisystem D intervention, along with counseling. As detailed below, the weight losses observed in the clinical trials are corroborated by real-world customer results.

3. Fabricatore AN et al. Reduction in glycemic variability and hyperglycemia with a low-glycemic index portion-controlled diet in persons with type 2 diabetes. Presented at the 72nd Annual Scientific Sessions of the American Diabetes Association. Philadelphia, PA June 10, 2012.
Click to view

This randomized cross-over trial employed continuous glucose monitoring (CGM) to assess multiple indicators of glycemic variability and stability in obese adults with type 2 diabetes. Subjects served as their own controls, consuming their usual diet and Nutrisystem D, in random order, for two weeks each, separated by a one-week washout period. During consumption of Nutrisystem D, participants had significantly lower average blood glucose (137.2 vs. 148.9 mg/dl, $p < 0.01$) and significantly less glycemic variability, as measured by standard deviation (31.8 vs. 36.1 mg/dl, $p < 0.04$) and interquartile range (38.9 vs. 45.0 mg/dl, $p < 0.05$) of blood glucose values. Additionally, participants recorded significantly fewer values in the hyperglycemic range (i.e., > 180 mg/dl; 13.4% vs. 21.0% of values, $p < 0.03$) without a significant increase in hypoglycemic values (i.e., < 70 mg/dl; 3.3% vs. 1.3%, $p = 0.19$). The figure below shows subjects' average blood glucose tracings during consumption of the portion-controlled diet (i.e., Nutrisystem D) versus their usual diet.



Customer Studies

1. Daggy BP et al. Trial participants and paying customers achieved similar weight losses with a commercial weight loss program for type 2 diabetes. Diabetes 2011; 60 (Suppl. 1); A702.
Click here to view abstract.

Nutrisystem researchers attempted to determine whether the results of the Foster et al. (2009) clinical trial were representative of the outcomes achieved by actual Nutrisystem D customers who were not participating in a structured trial. Nutrisystem D customers who used Nutrisystem's online weight-tracking tool to record their weight at baseline (i.e., time of initial purchase) and three months later (i.e., to match the length of the intervention in the clinical trial) were included in the analysis. The sample of 5,588 customers (64% women, mean age = 52.5 y, mean weight = 107.5 kg, mean BMI = 37.6 kg/m2) achieved an average 3-month weight loss of 8.2 kg, which represented a 7.6% reduction in initial body weight. By comparison, participants in the Foster et al. trial also lost 8.2 kg, representing a 7.1% weight loss. Approximately two-thirds of trial participants (67.7%) lost at least 5% of their initial weight, compared with over three-quarters (78.4%) of customers who reached that target. Thus, it appears that actual Nutrisystem D customers achieved similar weight losses to those achieved in a clinical trial.

2. Fabricatore AN et al. Results not typical? Subjective and objective success in a commercial weight loss program. Presented at the Annual Scientific Meeting of The Obesity Society. Orlando, FL. October 2, 2011.
Click here to view abstract.

Advertisements and testimonials for commercial weight loss programs (including Nutrisystem) often depict dramatic results that must be disclaimed as "not typical." This study attempted to define the typical results achieved by Nutrisystem customers. The only criterion for inclusion in the analysis was that the customer recorded their weight at baseline and at 3 months, which yielded a sample of 103,693 customers (70% women, mean age 46.9 y, mean weight = 216.4 lb, mean BMI = 34.3 kg/m2). The average weight loss at 3 months was 18.2 lb, representing an 8.3% reduction in initial weight. Although few customers (4.5%) reached their self-selected weight loss goal (mean goal = 54 lb loss) at 3 months, nearly four-fifths (79.4%) achieved at least a 5% weight loss in 3 months, including 33% of customers who lost 10% or more of their starting weight. This analysis suggested that the typical result for Nutrisystem customers who maintained some level of engagement for 3 months was a clinically meaningful weight loss.

3. Daggy BP et al. Holiday weight change in a commercial weight loss program. Presented at Advances and Controversies in Clinical Nutrition (a meeting of the American Society for Nutrition). San Francisco, CA. February 26, 2011.
Click here to view abstract.

Nutrisystem Supports Clinical Research

Nutrisystem is proud to partner with a number of academic institutions to support clinical investigations that include Nutrisystem® products and programs. Support mechanisms include investigator-initiated grants, in-kind product donations, and access to de-identified data. Please direct all inquiries to **research@nutrisystem.com**.