A Randomized, Double-Blind, Controlled, Parallel Study to Assess Effects of Personalized Weight Loss Programs on Body Weight and Anthropometric Measures in Adults with Overweight and Obesity

Background: The role of commercially available weight loss programs has continued to receive increased attention by the scientific community and consumers. One approach shown to be useful in supporting weight loss is provision of pre-portioned foods and beverages (i.e., meal replacements or portion and calorie controlled foods), especially compared to more conventional dietary advice, such as self-selected diets based on general concepts like variety and moderation. However, each commercial program is unique in their approach and support, notably not all provide pre-portioned foods and beverages. Further, commercial programs offer varying degrees of personalization so data from clinical trials documenting the degree of weight loss and related outcomes achievable with each commercial program are needed.

Objective: The primary objective of this trial was to determine if the Nutrisystem (NS) program with or without a Hydration Booster (HB) containing a proprietary blend of novel ingredients could aid in weight loss in overweight and obese adults over a 28-day period.

Methods: Eligible adults with overweight/obesity were enrolled and randomized to the Nutrisystem (NS) program with either HB or placebo (PLA). Both HB and PLA products were prepared with water for consumption. The intervention was 28 days. During the first week, subjects consumed the NS program diet providing approximately 1000 kcal/day, including Nutrisystem pre-packaged, portion-controlled foods and shakes. In addition to the NS foods and shakes, participants were able to add-in unlimited non-starchy vegetables. Following the first 7 days, subjects consumed a personalized diet based on their unique metabolism and self-selected body type for 21 days, which accounted for approximately 30-60% of their daily calorie target on average. The SmartAdapt® feature within the Nutrisystem NuMi app provided their personalized daily calorie goal (ranging from 1,200 to 2,500 calories) and meal plan. They were also instructed to prepare two breakfasts, two lunches, two dinners and two snacks (four snacks for men) on their own each week, consistent with the Nutrisystem Flex® meal formula. Subjects were instructed to maintain their activities of daily living and include at least 30 min of physical activity daily, consistent with the NS My Daily 3 recommendations. All subjects had access to NS weight loss coaches and to the NuMi app. The primary outcome of interest was the within-group change (actual and percentage) in body weight from baseline to Day 29 for all study subjects. A secondary outcome included between and within groups change in body weight at all timepoints measured post-randomization (Day 8, Day 15, Day 22, Day 29). Results presented were derived from a PP (per protocol) sample and comparisons were made with a repeated measures analysis of covariance (ANCOVA) model and an ANCOVA model.

The study and statistical analyses were conducted by an independent contract research organization (Biofortis Clinical Research, Addison, IL). The study was sponsored by Nutrisystem, Inc. Data on file.

Results: Of the 183 randomized subjects, 127 (F/M: 76/51) were included in the PP sample based on compliance with study conduct and randomized to the NS program with either HB [N = 62 (F/M: 39/23)] or placebo [PLA, N = 65 (F/M: 37/28)]. There were no notable differences between subjects included in the PP and those not included in the PP. Subjects (mean ± standard error of the mean: 48.5 ± 0.9 years old; screening BMI of 34.3 ± 0.4 kg/m^2) lost a significant amount of weight at all time points post-randomization on the NS program with either HB or PLA (estimated from repeated measures ANCOVA, $P < 0.05$; **Table 1**). After the first 7 days on the NS program, participants without the Hydration Booster lost an average of 5.1 pounds. Further, 20% of participants lost at least 7 pounds in the first 7 days on the Nutrisystem program.

Conclusion: The Nutrisystem program with and without the addition of a Hydration Booster using a proprietary blend of novel ingredients resulted in significant changes in body weight over a four-week period.

Table 1. Unadjusted change [Mean (95% confidence interval)] in body weight (lb.) over time in all (N = 127) and male subjects (N = 51) in the PP sample on the Nutrisystem Program with or without Hydration Booster*,[1]

Time Point (day)	Group	Change in body weight (lbs.)
8	Placebo	-5.14 (-5.84, -4.41)
	Hydration Booster	-4.74 (-5.49, -3.97)
15	Placebo	-6.53 (-7.39, -5.69)
	Hydration Booster	-5.95 (-6.81, -5.09)
22	Placebo	-7.81 (-8.78, -6.84)
	Hydration Booster	-7.10 (-8.14, -6.04)
29	Placebo	-9.22 (-10.52, -7.89)
	Hydration Booster	-8.31 (-9.57, -7.03)

*All within group comparisons are significant with the repeated measures model.

[1] The conversion factor is 2.205 lb./1 kg.

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