A Prospective Clinical Evaluation of the South Beach Diet to Aid in Weight Loss and Affect Body Circumference Measurements in Overweight and Obese Adults.

Many commercial products/diet plans are readily available to the weight conscious consumer; however, evidence specific to their tolerance and weight-loss promoting effectiveness is often lacking.

Objective:

The primary aim of this study was to determine if the South Beach Diet (SBD) can aid in weight loss in generally healthy overweight and obese people over a 28-d (4-week) period. A secondary objective was to learn the effects of the diet on body composition and circumference measurements, along with measures of metabolic health (blood pressure, glucose, insulin, and lipoprotein lipids), circulating testosterone levels (males only), gastrointestinal symptoms, and self-reported sleep quality, energy, and appetitive sensations.

Methods: 31 overweight/obese adults (n = 20 women, n = 11 men) with a mean (± standard error of the mean) age of 46.4 ± 1.4 y and body mass index (BMI) of 34.4 ± 0.8 kg/m^2 at screening were enrolled to follow a portion-controlled, meal-based SBD nutrition program. Changes in body weight, body fat mass (measured via dual energy x-ray absorptiometry), total body circumference (chest + waist + hip + dominant arm + dominant thigh), waist circumference, and waist + hip circumference were outcomes of primary interest. Results presented were derived from an intent-to-treat population (N = 31) and a per protocol population (N = 3), wherein 3 subjects were excluded from analysis for early termination from study participation.

Results: As shown in the following table, the participants experienced statistically significant changes in body weight, total body circumference, waist circumference, waist + hip circumference, and body fat mass at all timepoints ($P < 0.05$ for all change from baseline comparisons).

Conclusion: The portion-controlled, meal-based SBD nutrition program resulted in meaningful reductions in body weight, total body circumference, and body fat mass over a 4-week period.

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

Parameter	ITT[1] (N = 31)	ITT with LOCF (N = 31)	PP (N = 28)
		Mean (95% CI)	
Body Weight (kg)			
Baseline	97.4 (90.9, 103.9)	97.4 (90.9, 103.9)	97.0 (90.0, 104.0)
Δ Week 1	-2.6 (-3.2, -2.1)*(r)	-2.6 (-3.1, -2.0)*(r)	-2.7 (-3.3, -2.2)*(r)
Δ Week 2	-3.4 (-4.1, -2.8)*(r)	-3.2 (-3.9, -2.6)*(r)	-3.4 (-4.1, -2.8)*(r)
Δ Week 3	-4.0 (-4.8, -3.3)*(r)	-3.8 (-4.6, -3.0)*(r)	-4.0 (-4.8, -3.3)*(r)
Δ Week 4	-4.6 (-5.4, -3.8)*(r)	-4.3 (-5.2, -3.5)*(r)	-4.6 (-5.4, -3.8)*(r)
Fat Mass (kg)			
Baseline	41.5 (38.0, 45.0)	n/a	41.0 (37.3, 44.8)
Δ Week 4	-2.8 (-3.4, -2.1)*	n/a	-2.8 (-3.4, -2.1)*
Total Body Circumference (cm)			
Baseline	441.0 (428.7, 453.3)	441.0 (428.7, 453.3)	441.0 (427.9, 454.2)
Δ Week 1	-4.2 (-5.8, -2.5)*	-3.9 (-5.6, -2.3)*	-4.3 (-6.0, -2.6)*(r)
Δ Week 2	-6.9 (-9.1, -4.7)*	-6.4 (-8.5, -4.2)*	-6.9 (-9.1, -4.7)*(r)
Δ Week 3	-8.3 (-10.4, -6.2)*	-7.7 (-9.8, -5.5)*	-8.3 (-10.4, -6.2)*(r)
Δ Week 4	-9.8 (-12.2, -7.4)*	-9.1 (-11.5, -6.6)*	-9.8 (-12.2, -7.4)*(r)
Waist Circumference (cm)			
Baseline	108.4 (104.0, 112.8)	108.4 (104.0, 112.8)	108.6 (103.9, 113.3)
Δ Week 1	-0.9 (-1.9, 0.1)*(r)	-0.9 (-1.9, 0.1)*(r)	-1.0 (-2.0, 0.04)*(r)
Δ Week 2	-2.0 (-3.0, -1.0)*(r)	-1.8 (-2.8, -0.9)*(r)	-2.0 (-3.0, -1.0)*(r)
Δ Week 3	-2.3 (-3.4, -1.3)*(r)	-2.1 (-3.1, -1.2)*(r)	-2.3 (-3.4, -1.3)*(r)
Δ Week 4	-3.3 (-4.4, -2.2)*(r)	-3.0 (-4.2, -1.9)*(r)	-3.3 (-4.4, -2.2)*(r)
Waist+Hip Circumference (cm)			
Baseline	227.5 (220.6, 234.4)	227.5 (220.6, 234.4)	227.2 (219.9, 234.6)
Δ Week 1	-2.0 (-3.2, -0.7)*(r)	-1.8 (-3.1, -0.6)*(r)	-1.9 (-3.2, -0.6)*(r)
Δ Week 2	-3.8 (-5.1, -2.4)*(r)	-3.5 (-4.8, -2.2)*(r)	-3.8 (-5.1, -2.4)*(r)
Δ Week 3	-4.1 (-5.5, -2.7)*(r)	-3.9 (-5.3, -2.4)*(r)	-4.1 (-5.5, -2.7)*(r)
Δ Week 4	-5.5 (-7.1, -3.9)*(r)	-5.2 (-6.7, -3.6)*(r)	-5.5 (-7.1, -3.9)*(r)

Abbreviations: Δ, change from baseline; ITT, Intent-to-Treat; LOCF, last observation carried forward; N, sample size; n/a, not applicable; PP, Per Protocol; SBD, South Beach Diet.

[1]Results for the ITT population without the use of LOCF as an imputation approach for missing data.

*P-value < 0.05 for the within-group change from baseline at each time point. (r) after this symbol indicates P values were generated based on rank-transformed data.

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