

# Tolerability and efficacy of a physician-supervised, structured meal replacement program in body composition and weight management: outcomes from a workplace setting



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## BACKGROUND AND OBJECTIVES

The prevalence of overweight and obesity is a growing problem in the United States. More than two-thirds of American adults (age  $\geq 20$ ) and almost one-third of children (age  $< 20$ ) are overweight or obese. Obesity increases the risk of developing many serious diseases and health conditions. As a result, obesity and its related comorbidities cost U.S. healthcare system more than \$190 billion annually. Weight management including diet and exercise may be the most effective option to combat the obesity epidemic.

Structured meal replacement plans that are hypocaloric, low in glycemic index, convenient and optimized with micro- and macronutrients have been shown to promote weight loss by providing convenient alternatives to the typical high fat, hyperglycemic, and supersized American diets.

The current study examined the effects of a physician supervised, structured meal replacement program combined with moderate exercise on weight loss and body composition in a work place setting as an employee wellness weight loss challenge. Meal replacement products were designed to deliver high levels of protein with added leucine, and pre- and probiotic blend. Participants received free physician consultations and free meal replacement products and were incentivized with prizes based on percent of initial body weight lost.

The findings showed that this program was well-tolerated and promoted significant and clinically meaningful weight loss accompanied by a significant body fat mass reduction. Long-term studies are warranted to evaluate the effects of this program on weight maintenance.

## METHODS

**Design:** The study was conducted in a workplace setting. Participants were advised by a physician to use a customizable 3-meal-a-day structured meal plan: two meal replacements and one balanced dinner daily.

**Diet Plan:** Meal replacements include low-glycemic shakes providing approximately 24 g of protein, 3 g of fat, 30 g carbohydrate, 6 g of fiber, 1 billion CFU of probiotics and 23 vitamins and minerals for a total of 260 Calories per serving. Snacks provide 6 -10 g of protein, 2 - 3 g of fiber, and 100 - 140 Calories per serving. Dinner recipes typically consist of 4 oz. protein from skinless chicken, pork tenderloin or lean beef; 1 cup of steamed vegetables; a small serving of carbohydrate such as a small baked potato,  $\frac{1}{3}$  cup of brown rice or a 6" tortilla; a small salad of healthy leafy greens with low-calorie dressing.

**Data Collection:** Seven brief physician-supervised consultations and weigh-ins were scheduled, at baseline and at two-week intervals thereafter for 12 weeks. Bioimpedance data were collected at baseline and week 12. To be included in the statistical analysis, participants were required to complete baseline and week 12 bioimpedance measurements.

**Statistics:** Missing biweekly weigh-in data were imputed using last-observation-carried-forward method. Student's *t*-test was used for comparisons between two data points. For comparison of multiple data points, ANOVA was used. *P*-values less than 0.05 were considered to be statistically significant.



## RESULTS

Table 1. Baseline demographic data

Parameter	Value (n = 24)
Female [n (%)]	14 (58.3)
Age (year)	46.5 $\pm$ 2.5
Weight (lb)	179.0 $\pm$ 7.0
Height (in)	65.9 $\pm$ 0.8
BMI (kg/m <sup>2</sup> )	28.8 $\pm$ 0.8

Values are expressed in Mean  $\pm$  SEM where applicable.

Table 2. Summary of change in weight category

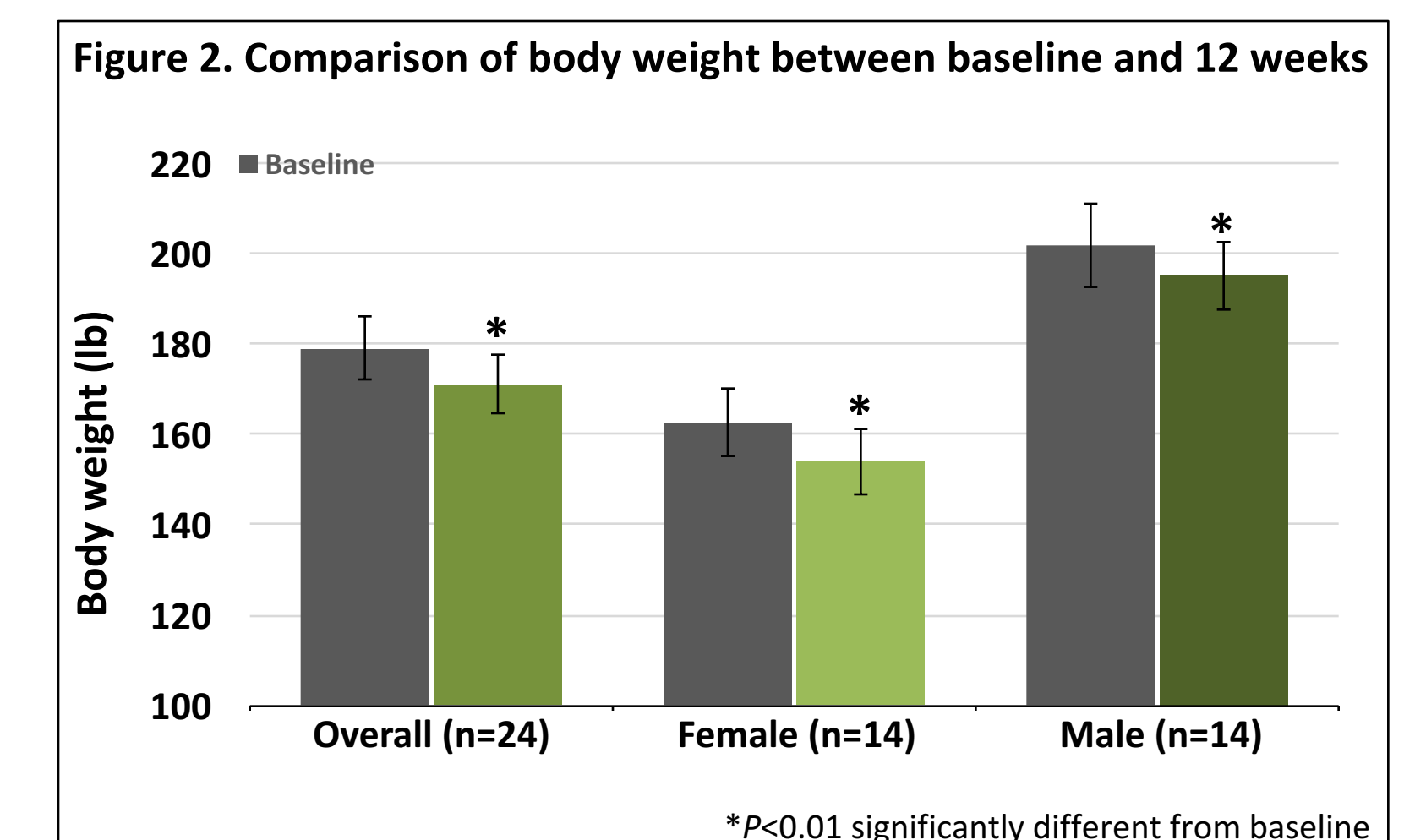
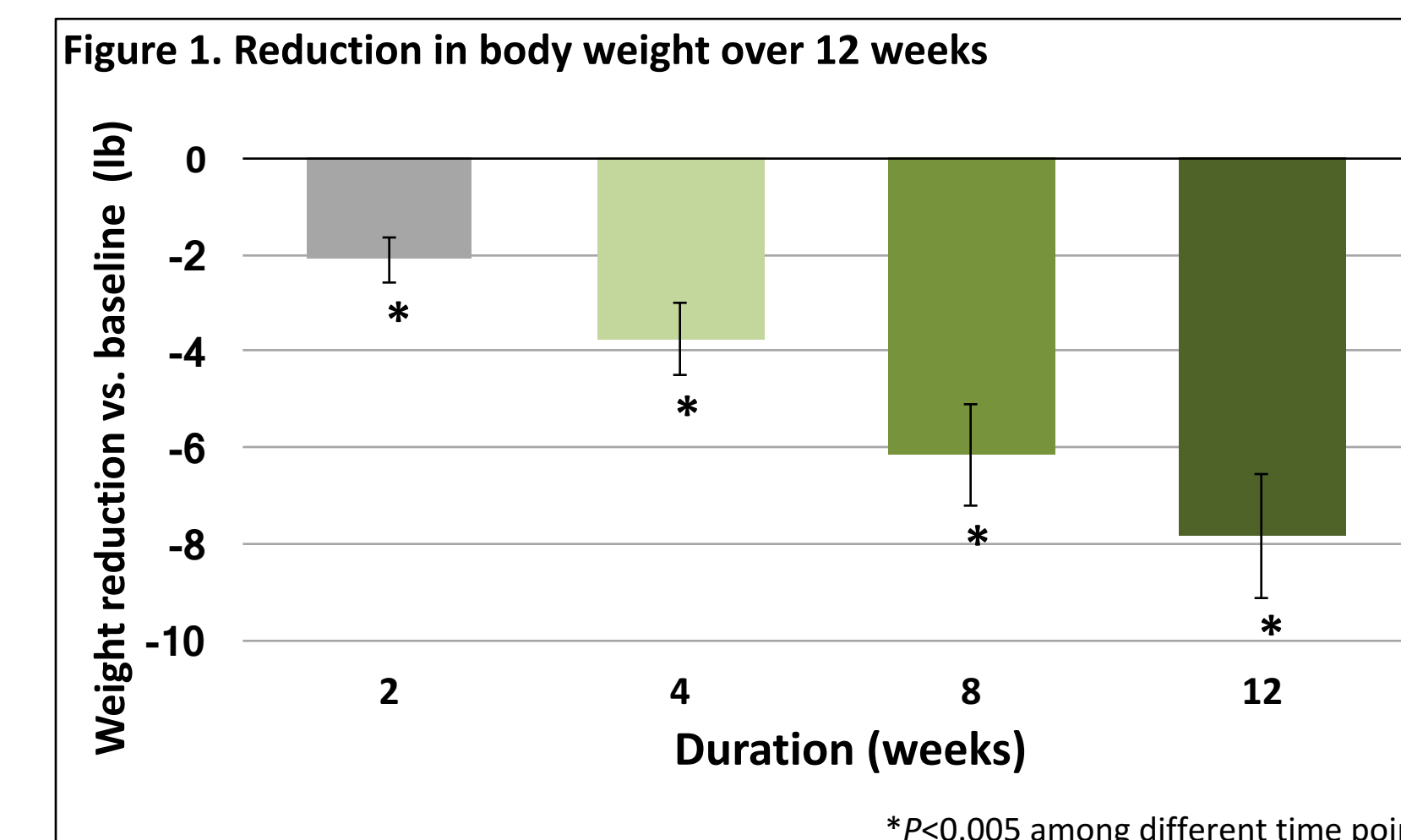
Parameter	Baseline	12 Weeks	% Change
BMI (kg/m <sup>2</sup> )	28.8 $\pm$ 0.8	27.5 $\pm$ 0.7*	-4.5
Obese (n)	8	5	-37.5
Overweight (n)	10	9	-10.0
Normal (n)	6	6	16.7

n = 24; \*P < 0.0001

Table 3. Summary of change in body composition from baseline

	Parameter	Baseline (Mean $\pm$ SEM)	12 Weeks (Mean $\pm$ SEM)	P-value	Net Change
Overall (n=24)	FM (lb)	59.2 $\pm$ 3.3	50.1 $\pm$ 2.9	<0.0001*	-9.14
	FFM (lb)	119.8 $\pm$ 5.2	121.1 $\pm$ 5.1	=0.35	+1.30
	Weight (lb)	179.0 $\pm$ 7.0	171.2 $\pm$ 6.6	<0.0001*	-7.84
	Waist Circumference (in)	39.2 $\pm$ 0.9	37.2 $\pm$ 0.8	<0.0001*	-1.91
	Hip Circumference (in)	42.7 $\pm$ 0.7	41.7 $\pm$ 0.7	<0.003*	-1.03
	Waist/Hip Ratio	0.92 $\pm$ 0.01	0.89 $\pm$ 0.01	<0.02*	-0.02
Female (n=14)	FM (lb)	61.2 $\pm$ 5.0	48.0 $\pm$ 4.6	<0.001*	-13.20
	FFM (lb)	102.5 $\pm$ 3.3	106.0 $\pm$ 4.3	=0.09	+3.48
	Weight (lb)	162.6 $\pm$ 7.6	154.0 $\pm$ 7.1	<0.0005*	-8.66
	Waist Circumference (in)	37.2 $\pm$ 1.2	35.4 $\pm$ 1.0	<0.005*	-1.85
	Hip Circumference (in)	42.8 $\pm$ 1.1	41.5 $\pm$ 1.1	<0.02*	-1.32
	Waist/Hip Ratio	0.87 $\pm$ 0.01	0.85 $\pm$ 0.01	=0.2	-0.02
Male (n=10)	FM (lb)	57.9 $\pm$ 3.8	52.9 $\pm$ 2.5	<0.05*	-4.92
	FFM (lb)	144.0 $\pm$ 5.8	142.3 $\pm$ 5.8	=0.3	-1.76
	Weight (lb)	201.9 $\pm$ 9.1	195.2 $\pm$ 7.6	<0.01*	-6.68
	Waist Circumference (in)	41.9 $\pm$ 0.8	39.9 $\pm$ 0.7	<0.0001*	-2.01
	Hip Circumference (in)	42.6 $\pm$ 0.7	42.0 $\pm$ 0.5	=0.1	-0.63
	Waist/Hip Ratio	0.98 $\pm$ 0.01	0.95 $\pm$ 0.01	<0.05*	-0.03

\*Significantly different from baseline. FM = Fat Mass; FFM = Fat Free Mass



## SUMMARY

- The program was well tolerated. Six of the 30 enrolled participants dropped out due to scheduling/personal reasons.
- Significant loss in fat mass (-9.14 lb) and reduction in net body weight (-7.84 lb) were observed after 12 weeks (Table 3).
- Significant weight loss was observed as early as in two weeks. In general, men lost significantly more weight than women (Table 3, Fig 2).
- Significant decrease in BMI by 1.3 kg/m<sup>2</sup> was seen after 12 weeks resulting in categorical shift in weight classification such that 3 out of 8 obese participants shifted to overweight category. Out of the 10 overweight participants, 1 shifted to normal weight category. No categorical change was observed in the normal weight cohort (Table 2).
- Waist (-1.9 in) and hip (-1.0 in) circumferences were significantly reduced resulting in a drop of one pant/dress size (Table 3).

## CONCLUSIONS

- This program was well tolerated and resulted in significant and clinically meaningful weight/fat loss after 12 weeks.
- Long-term studies are warranted to evaluate the effects of this program on fat loss and weight maintenance.