OPTIWIN DEMONSTRATES THE EFFICACY OF THE OPTIFAST® PROGRAM

VOLUME 1

The OPTIFAST® program, a clinically proven weight loss program, continues to deliver weight loss for patients and improve obesity-related comorbidities as a result of the weight loss.[1-3] The recently conducted **OPTIWIN Study** demonstrated that a behavioral weight loss intervention using total meal replacement (the OPTIFAST® program) is more effective than a reduced-calorie, food-based intervention and resulted in significantly greater weight loss at 26 and 52 weeks. OPTIWIN is the largest randomized controlled trial of total meal replacement ever conducted in the United States.[4]

STUDY DESIGN

- 52-week, multicenter, open-label, randomized, controlled trial in adults with a BMI of 30 to 55 kg/m^2, with a 26-week weight loss phase and a 26-week weight maintenance phase
- Participants (N=330) were stratified by type 2 diabetes status and randomized to the OPTIFAST® program (a total meal replacement diet [800-960 kcal/d] with lifestyle intervention) or to a reduced-energy (-500 to -750 kcal/d) food-based diet with lifestyle intervention based on the Diabetes Prevention Program (DPP)

PRIMARY ENDPOINTS*

- Demonstrate the efficacy of the OPTIFAST® program by comparing the percent change in body weight from baseline to 26 weeks (weight loss phase) and baseline to 52 weeks (weight loss + maintenance phase) between the OPTIFAST® program and a food-based diet

BMI=body mass index.

*Primary endpoints were analyzed using a modified intent-to-treat (mITT) approach, including all randomized participants who initiated treatment with ≥1 follow-up weight measure. Missing data were imputed using last observation carried forward.[4]

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INTERVENTIONS

	OPTIFAST® program	Food-based modified DPP (active-control group)
Dietary plan	Total meal replacement for up to 16 weeks, then gradual reintroduction of food while continuing with 1 to 2 OPTIFAST® meal replacement products per day. Calorie level was based upon BMI	500-750 kcal reduction from estimated total energy expenditure (25%-30% fat)
Exercise plan	150-180 minutes/week of moderate to vigorous intensity exercise	150-180 minutes/week of moderate to vigorous intensity exercise
Behavioral counseling (group)	Weekly group sessions	Weekly group sessions
Behavioral counseling (individual)	Individual counseling sessions per schedule	Individual counseling sessions per schedule

STUDY POPULATION

- 330 patients were randomized and 273 were included in the analyses
- 229 patients completed the study: 116 in the OPTIFAST® program group and 113 in the food-based group
- Mean baseline body weight was 239±48.6 lb

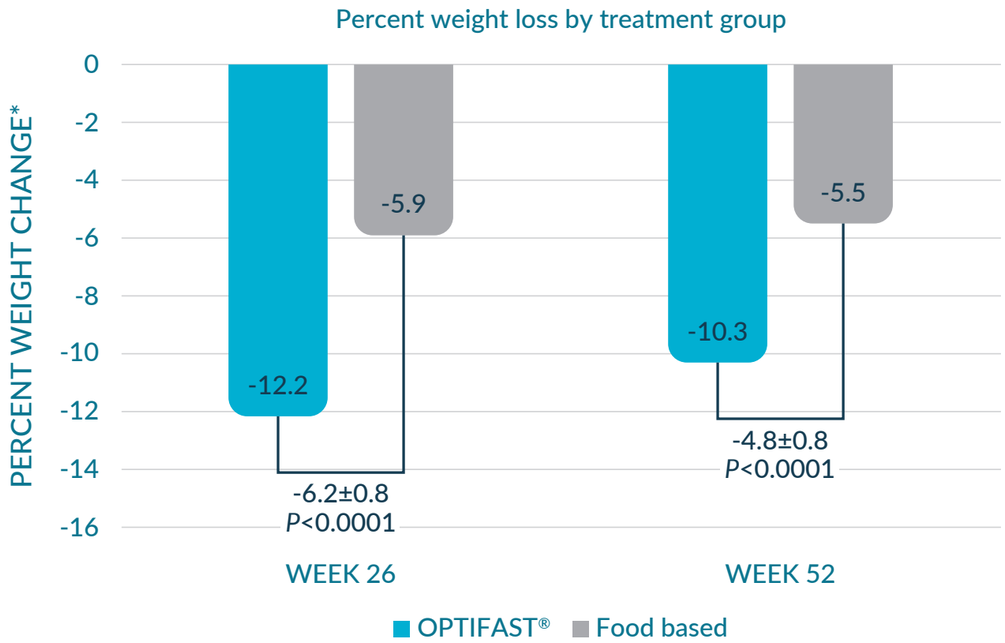
Baseline characteristics of treatment groups (mITT population)[4]

	OPTIFAST® program (n=135)	Food-based program (n=138)
Age in years, mean (SD)	47 (11.2)	47.2 (11.3)
Sex, n (%)		
Male	19 (14.1)	29 (21.0)
Female	116 (85.9)	109 (79.0)
Race, n (%)		
White	100 (74.1)	95 (68.8)
African American	22 (16.3)	37 (26.8)
Asian/Pacific Islander	4 (3)	2 (1.4)
Hispanic	5 (3.7)	4 (2.9)
Other	4 (3)	0
Weight in lb, mean (SD)	235 (45.8)	241.8 (51.1)
BMI in kg/m^2, mean (SD)	38.4 (5.5)	39.2 (6.2)
BMI categorization, n (%)		
Overweight (25-29.9 kg/m^2)	0	3 (2.2)
Obesity Class I (30-34.9 kg/m^2)	44 (32.6)	38 (27.5)
Obesity Class II (35-39.9 kg/m^2)	43 (31.9)	36 (26.1)
Obesity Class III (≥40 kg/m^2)	48 (35.6)	61 (44.2)
Type 2 diabetes diagnosis, n (%)	13 (9.6)	20 (14.5)
Prediabetes diagnosis, n (%)	57 (42.2)	49 (35.5)
Number of previous weight loss attempts, mean (SD)	5.5 (8.3)	7.0 (9.2)
Typical weight loss with previous weight loss attempts in lb, mean (SD)	4.6 (11.7)	5.3 (14.5)

RESULTS

Overall, the study demonstrated that a weight loss intervention using total meal replacement with the OPTIFAST® program was more effective than a reduced-calorie food-based intervention.

OPTIFAST® program patients lose approximately 12% of their initial body weight at 26 weeks and maintain 10% weight loss at 52 weeks

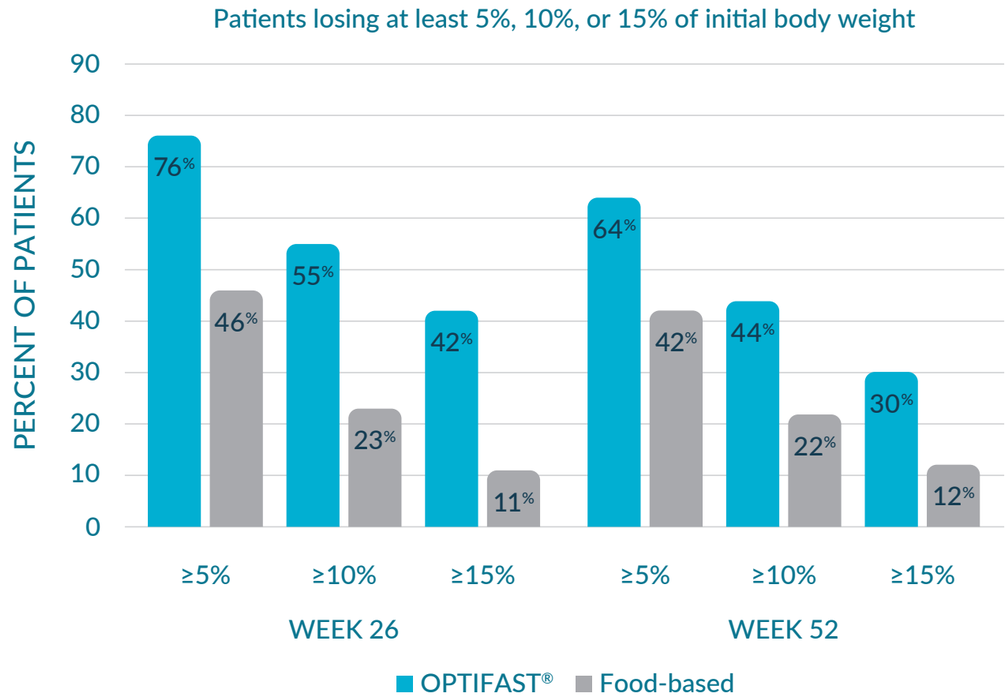


*Percent weight loss values are least square means from a linear mixed model. The linear mixed model contains a random intercept subject effect; fixed visit effect; fixed treatment effect; fixed baseline body weight effect; a treatment-by-visit interaction term; and covariates, including age, sex, race, site, and reported baseline diabetes status.

The OPTIFAST® program is more effective than the standard of care

- Patients in the OPTIFAST® program group lose twice as much weight in 26 weeks as patients who receive standard of care

A higher proportion of OPTIFAST® program participants lose clinically meaningful amounts of weight at 26 and 52 weeks



Note: OPTIFAST® group, n=135; Food-based group, n=138

- **At 26 weeks:** 42% of patients in the OPTIFAST® program group lose at least 15% of their initial body weight vs 11% in the food-based group (*P*<0.001)
- **At 52 weeks:** 30% of patients in the OPTIFAST® program group maintained at least 15% of their initial body weight loss vs 12% in the food-based group (*P*<0.001)

IN THE OPTIWIN STUDY

- 101 patients (30.6%) discontinued the study and there were no differences in the discontinuation rate between the 2 study groups
- Mild or moderate adverse events (AEs) were reported by 76.8% of patients in the OPTIFAST® program group and 62.7% of patients in the food-based group
- Serious AEs were reported by 4.5% and 3.3% of patients in the OPTIFAST® program and food-based groups, respectively
  - No serious AEs were related to the OPTIFAST® products

STAY TUNED AS NEW OPTIWIN RESULTS ARE RELEASED

In the coming months, additional outcomes of the OPTIWIN study will be available, including:

- Changes in obesity-related comorbidities (blood pressure, cholesterol levels, HbA_{1c}, diabetes medications, and more)
- Patient adherence to the interventions
- Changes in waist circumference, waist-to-hip ratio, BMI, and body composition
- Quality-of-life measures

Continue to help your patients WIN with the OPTIFAST® program

The science-based program that delivers weight loss for health gains

1. Ard JD, Schroeder MC, Kivilaid K, et al. Practical application of a comprehensive weight management program in patients with and without metabolic syndrome. *J Obes Weight Loss Ther*. 2014;S4:007. **2.** Wadden TA, Foster GD, Letizia KA, et al. A multicenter evaluation of a proprietary weight reduction program for the treatment of marked obesity. *Arch Intern Med*. 1992;152(5):961-966. **3.** Drawert S, Bedford K, Largent D. Change in glucose, blood pressure, and cholesterol with weight loss in medically obese patients. *Obesity Res*. 1996;4(S1):67S. **4.** Ard JD, Auriemma A, Coburn S, et al. Effectiveness of a total meal replacement program (OPTIFAST® Program) compared with a reduced-energy food based diet plan on weight loss: results from the OPTIWIN study. Poster presented at: 25th European Congress on Obesity; May 23-26, 2018; Vienna, Austria.

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