OPTIWIN DEMONSTRATES IMPROVED GLYCEMIC CONTROL WITH THE OPTIFAST® PROGRAM

VOLUME 2

The OPTIFAST® program continues to deliver weight loss for patients resulting in improvements in obesity-related comorbidities, including glycemic outcomes.[1-3] The **OPTIWIN Study**,* a randomized, head-to-head study, demonstrated that a behavioral weight loss intervention using a total meal replacement diet (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. Additionally, the study demonstrated that the OPTIFAST® program has a greater impact on glycemic outcomes.[4]

STUDY OBJECTIVES†,[4]

- **Primary:** Compare the efficacy of the OPTIFAST® program with that of a reduced-calorie, food-based diet program for weight loss at 26 weeks and 52 weeks
- **Secondary:** Comparison of glycemic outcomes, including glycosylated hemoglobin (HbA1c), fasting blood glucose, and presence of diabetes or prediabetes, between patients in the OPTIFAST® program group or food-based group

Baseline characteristics—glycemic status

	OPTIFAST® program (n=135)	Food-based program (n=138)
Type 2 diabetes‡	13 (9.6%)	20 (14.5%)
Prediabetes	57 (42.2%)	49 (35.5%)

- 330 patients were randomized and 273 were included in the final analysis. Of those, 229 completed the study (116 in the OPTIFAST® group and 113 in the food-based group)

*52-week, multicenter, open-label, randomized, controlled trial in adults (aged 18 to 70 years) with a body mass index of 30 to 55 kg/m^2. Participants (N=330) were stratified by type 2 diabetes status and randomized to the OPTIFAST® program, a total meal replacement diet (800-1200 kcal/d) with lifestyle intervention, or a reduced-energy (-500 to -750 kcal/d) food-based diet with lifestyle intervention based on the Diabetes Prevention Program.[4]

†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]

‡As reported by patients at baseline.

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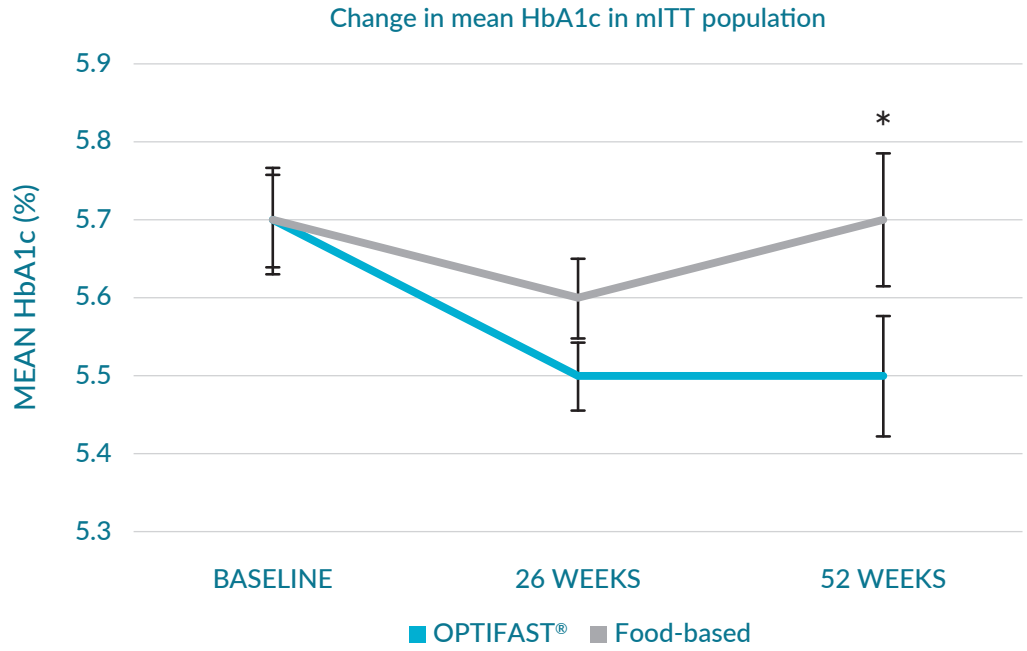
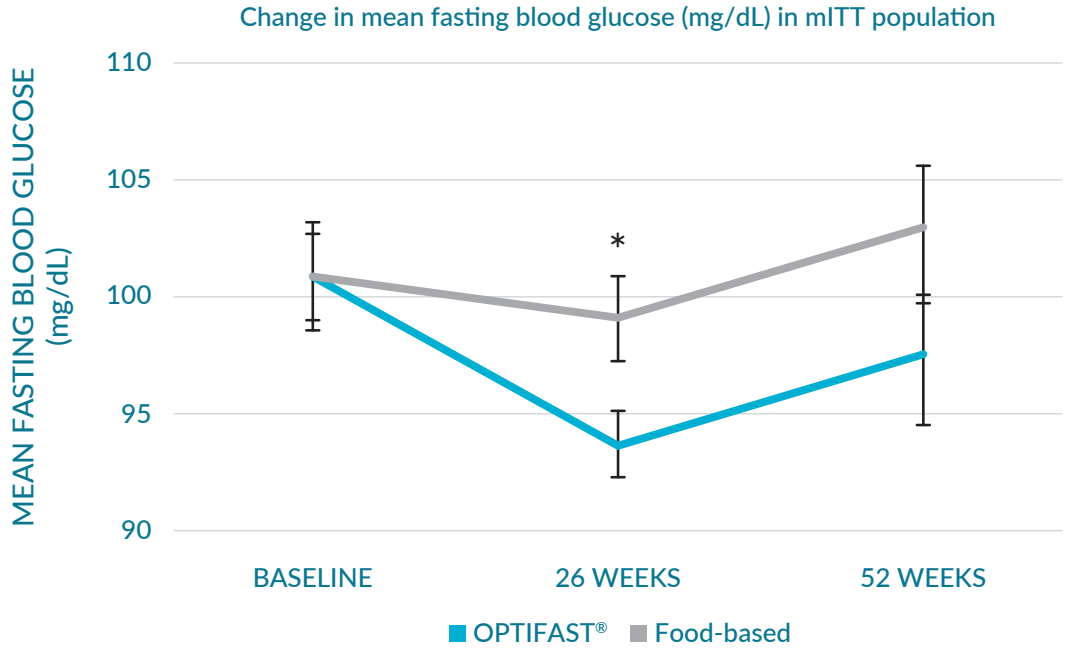
RESULTS

The OPTIWIN Study demonstrated that weight loss using total meal replacement with the OPTIFAST® program was more effective than a food-based intervention at improving glycemic outcomes, including HbA1c, fasting blood glucose, and status of diabetes.[4]

Patients in the OPTIFAST® program group had a significantly greater improvement in HbA1c than patients in the food-based group (*p<0.05)[4]



In the OPTIFAST® group, fasting glucose levels were significantly improved compared with the food-based group (*p<0.05)[4]

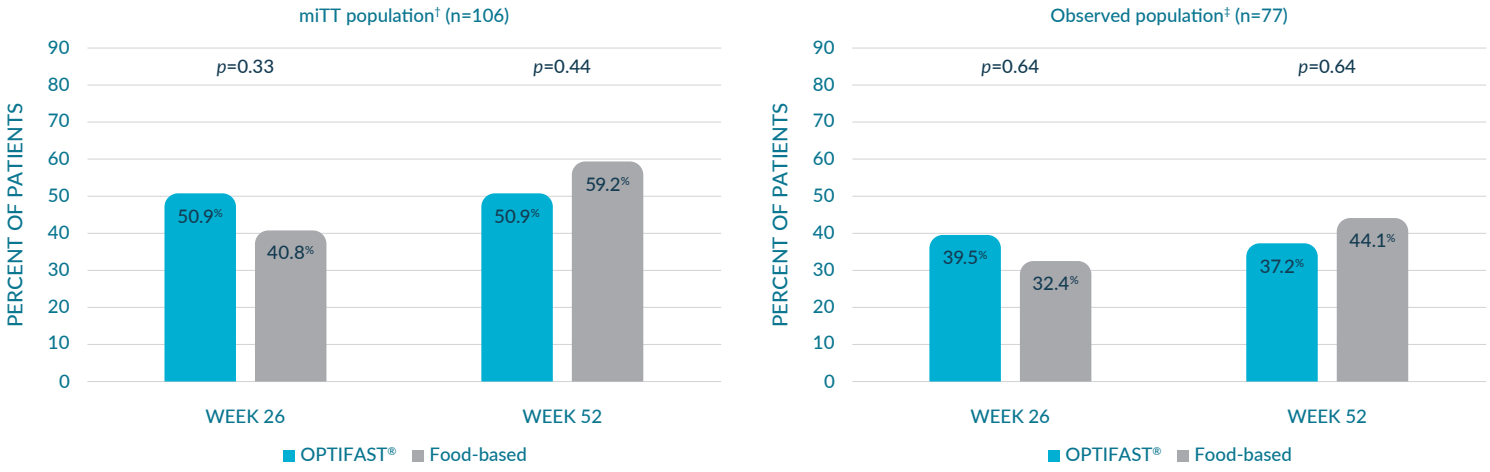


More patients in the OPTIFAST® program group no longer met the criteria for diabetes compared with patients in the food-based group in observed population analysis at 26 weeks[4]

Diabetes* at 26 and 52 weeks in patients with diabetes at baseline

Reduction in prevalence of prediabetes was not significantly different between the 2 groups

Prediabetes** at 26 and 52 weeks in patients with prediabetes at baseline



*Diabetes status = yes when HbA1c ≥6.5% or patient was receiving anti-diabetes treatment.

†mITT population had at least 1 measured weight during follow up; if diabetes status was missing at a follow-up timepoint, then the patient was categorized according to baseline status (last observation carried forward). Data analyzed using linear mixed models adjusted for baseline value, age, sex, site, race, and diabetes status.

‡Observed population only includes patients who received follow up at both 26 and 52 weeks.

**Prediabetes status = yes when HbA1c 5.7% to 6.4% without receiving anti-diabetes treatment.

IN THE OPTIWIN STUDY[4]

- A higher proportion of OPTIFAST® program patients lost clinically meaningful amounts of weight at 26 and 52 weeks
- OPTIFAST® program patients experienced a positive impact on their glycemic outcomes
- 101 patients (30.6%) discontinued the study and there were no differences in the discontinuation rate between the 2 study groups
- The most commonly reported adverse events (AEs) were constipation (18.7% and 2.7%), headache (17.4% and 4.7%), and dizziness (16.8% and 2.0%) in the OPTIFAST® group and the food-based groups, respectively
- 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 ADDITIONAL OPTIWIN RESULTS ARE RELEASED

- Changes in additional obesity-related comorbidities (blood pressure, cholesterol levels, and more)
- Patient adherence to the interventions
- Improvements 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.** Rothberg AE, Ard JD, Auriemma A, et al. Effect of a total meal replacement program compared with a reduced-energy, food-based diet plan on glycemic status: results from the OPTIWIN study. Poster presented at: American Diabetes Association 78th Scientific Sessions; June 22-26, 2018; Orlando, Florida.

www.OPTIFAST.com • 1-800-662-2540
Bridgewater, NJ 08807 U.S.A.

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