OPTIFAST® program continues to deliver weight loss for patients resulting in improvements in obesity-related comorbidities, including glycemic outcomes. 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.

**STUDY OBJECTIVES**

- **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**

<table>
<thead>
<tr>
<th></th>
<th>OPTIFAST® program (n=135)</th>
<th>Food-based program (n=138)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Type 2 diabetes‡</td>
<td>13 (9.6%)</td>
<td>20 (14.5%)</td>
</tr>
<tr>
<td>Prediabetes</td>
<td>57 (42.2%)</td>
<td>49 (35.5%)</td>
</tr>
</tbody>
</table>

- 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)

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*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/m². 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.*

*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.*

*As reported by patients at baseline.*
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.\textsuperscript{4}

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

In the OPTIFAST® group, fasting glucose levels were significantly improved compared with the food-based group (\(p<0.05\))\textsuperscript{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.

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

- **mITT population** (n=42)
  - Week 26: 58.8% OPTIFAST®, 72.0% Food-based
  - Week 52: 64.7% OPTIFAST®, 80.0% Food-based

- **Observed population** (n=30)
  - Week 26: 50.0% OPTIFAST®, 68.8% Food-based
  - Week 52: 57.1% OPTIFAST®, 75.0% Food-based

\[ p = 0.07 \] for mITT population and \[ p = 0.19 \] for observed population.

**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

- **mITT population** (n=106)
  - Week 26: 50.9% OPTIFAST®, 40.8% Food-based
  - Week 52: 59.2% OPTIFAST®, 59.2% Food-based

- **Observed population** (n=77)
  - Week 26: 39.5% OPTIFAST®, 32.4% Food-based
  - Week 52: 37.2% OPTIFAST®, 44.1% Food-based

\[ p = 0.33 \] for mITT population and \[ p = 0.44 \] for observed population.

**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

• 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