

# OPTIWIN STUDY

A YEAR-LONG RANDOMIZED CONTROLLED STUDY OF THE OPTIFAST® PROGRAM FOR WEIGHT LOSS

## PRIMARY ENDPOINT

Compare the efficacy of the OPTIFAST® program

VS

A reduced-calorie, food-based program

Weight loss at 26 weeks and 52 weeks

## STUDY DESIGN

52-WEEK, open-label, randomized trial at 9 US centers

Baseline → week 26 = active weight loss phase

Week 27 → week 52 = weight maintenance phase

## STUDY POPULATION AND METHODS

330 adults (aged 18–70 years) with BMI 30–55 kg/m<sup>2</sup> stratified by type 2 diabetes status

### OPTIFAST® PROGRAM (n=135 mITT\*)

- Total meal replacement up to 16 weeks (≥800 kcal/day, based on BMI; 40% carbohydrate, 40% protein, 20% fat), then gradual reintroduction of food
- **Maintenance:** Conventional food, encouraged 1–2 meal replacements per day

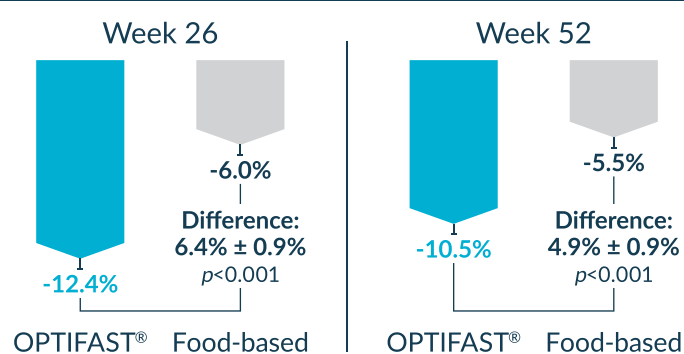
### FOOD-BASED PROGRAM (n=138 mITT\*)

- Reduced energy (–500 to –750 kcal/day, 25%–30% fat) diet based on a modified Diabetes Prevention Program for 26 weeks
- **Maintenance:** Increased energy intake to achieve weight maintenance

- 150–180 minutes/week of moderate to vigorous intensity exercise
- Group (weekly) and individual (per schedule) behavioral counseling sessions

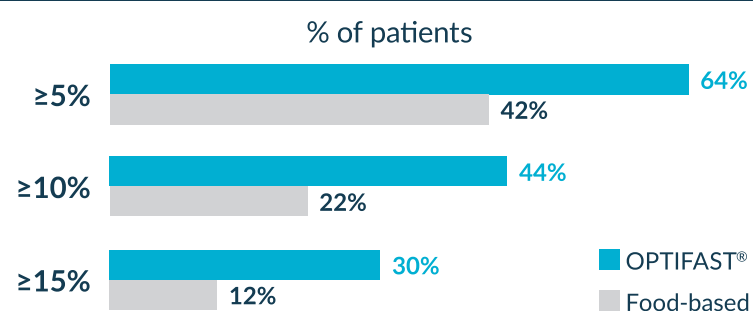
## RESULTS

### Mean percent weight loss



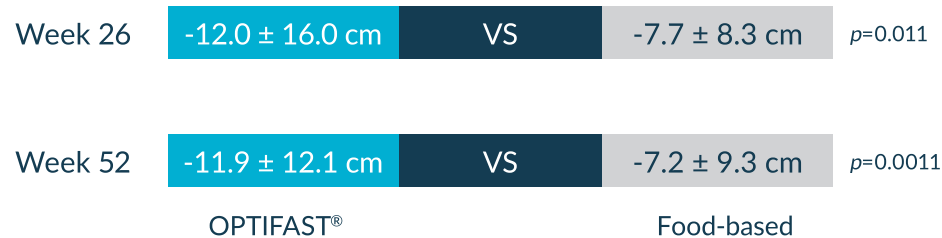
Patients lost **2x** as much weight using the OPTIFAST® program

### Clinically significant weight loss at Week 52†



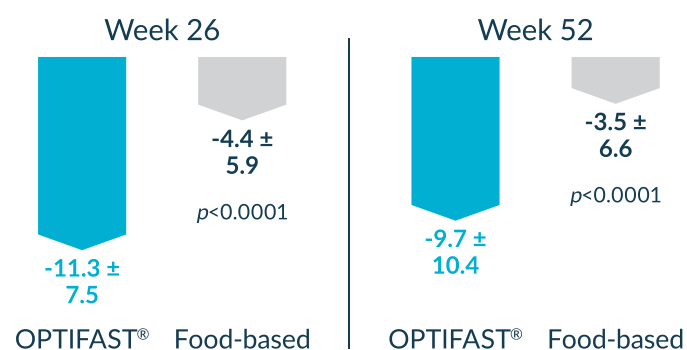
More OPTIFAST® program patients maintained clinically meaningful weight loss

### Mean change in waist circumference (cm)



Patients experienced **greater reductions in waist circumference** using the OPTIFAST® program

### Mean change in total fat mass (kg)



OPTIFAST® program patients achieved **greater reductions in total fat mass**

IN BOTH GROUPS:



Similar completion rates



Similar serious AE rates



Similar AE rates per contact

## CONCLUSION

The OPTIFAST® program resulted in **twice as much weight loss and higher rates of clinically meaningful weight loss**, versus a food-based intervention

BMI=body mass index.

\*The primary analysis was done in the modified intent-to-treat (mITT) population (n=273); the mITT population included all participants who started their assigned intervention and had at least 1 post-baseline weight.

†Differences between groups were statistically significant (p<0.05) at all time points.

Ard JD et al. Effectiveness of a total meal replacement program (OPTIFAST® program) on weight loss: results from the OPTIWIN study [published online November 13, 2018]. *Obesity*. 2018.

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