Nestlé HealthScience

News release

CLINICAL STUDY OF OPTIFAST® MEAL REPLACEMENT PROGRAM DEMONSTRATES SIGNIFICANT SUSTAINED WEIGHT LOSS IN PATIENTS WITH OBESITY

In the year-long OPTIWIN randomized, head-to-head, clinical trial, the OPTIFAST Program resulted in an average weight loss two-fold higher than a reduced-calorie, food-based diet and lifestyle intervention.

BRIDGEWATER, NJ, November 13, 2018 — Nestlé Health Science today announced the publication of positive results from the OPTIWIN study in *Obesity*,[1] the official peer-reviewed journal of The Obesity Society. OPTIWIN, which represents the largest year-long, randomized, clinical trial of a behavioral weight loss intervention with total meal replacement (TMR) conducted in the U.S., demonstrated significant benefits of the OPTIFAST program on both the magnitude of weight loss and the proportion of patients achieving clinically meaningful weight loss at 26 and 52 weeks. The results of the study add to the impressive body of scientific evidence demonstrating the weight-loss and related health benefits of the OPTIFAST Program.

“Obesity continues to be a significant and growing public health challenge. More than half of Americans could be affected by obesity by 2030 if current trends continue. This is complicated by the fact that trying to lose weight and keep it off is challenging for most. This study shows that the OPTIFAST Program can help with significant and sustained weight loss, even among those who have tried and failed to lose weight in the past,” said Dr. Jamy Ard, MD, Professor, Department of Epidemiology and Prevention and the Department of Medicine, Wake Forest University Baptist Medical Center and OPTIFAST Medical Director. “Participants in the OPTIFAST group had an average of 5.5 previous weight loss attempts and reported losing only about 5 pounds with most attempts; with the OPTIFAST Program, these participants achieved an average weight loss that was clinically significant.”

The OPTIFAST Program is a medically monitored weight loss program that combines meal replacement with behavioral counseling and personalized support. In the OPTIWIN study, participants were randomized to either the OPTIFAST Program (OP) or a behavioral intervention using a food-based diet (FB). For the first 12-16 weeks of the study, the OP group followed a TMR diet, consuming ≥800 kcal/day as portion-controlled, nutritionally complete meal replacements (shakes, bars and soups). TMR was followed by a gradual reintroduction of food through week 26, then a 6-month weight maintenance phase. Participants in the FB group received a comprehensive diet and lifestyle intervention that included a reduced-calorie (-500 to -750 kcal/day), food-based diet from weeks 1-26. Caloric intake was adjusted to achieve weight maintenance from weeks 27-52. The intervention provided to the comparator group was adapted from the Diabetes Prevention Program[2,3] and is considered to be a standard-of-care lifestyle intervention as recommended in the most recent Guideline for the Management of Overweight and Obesity in Adults from the American College of Cardiology, the American Heart Association and The Obesity Society.[4]

In addition to the respective dietary interventions, both groups in the OPTIWIN study were medically monitored, participated in individual and group behavioral counselling sessions, and received individualized prescriptions for physical activity with a graduated target of 150-180 minutes/week of moderate-to-vigorous exercise. Primary endpoints for the study were weight loss at 26 and 52 weeks, expressed as percentage of baseline weight lost. These endpoints were analyzed using a modified intent-to-treat approach, including all randomized participants who initiated treatment and had at least one follow-up weight measurement (n=273).

Significantly greater weight loss with the OPTIFAST Program, sustained through 52 weeks

At both 26 and 52 weeks, the OP group lost, on average, twice as much of their initial body weight as the FB group:

- At 26 weeks: 12.4% (SE 0.6) vs 6.0% (SE 0.6) of body weight lost (OP vs FB, respectively; p<0.001)
- At 52 weeks: 10.5% (SE 0.6) vs 5.5% (SE 0.6) of body weight lost (OP vs FB, respectively; p<0.001)

Additionally, the proportion of participants who achieved clinically meaningful weight loss (≥5%, ≥10%, and ≥15%) was significantly higher in the OP group. For example:

- At 26 weeks, 55% of the OP group lost at least 10% of their initial body weight vs 23% of the FB group (p<0.001)
- At 52 weeks, 44% of the OP group lost at least 10% of their initial body weight vs 22% of the FB group (p<0.001)

Greater improvements in waist circumference and body composition with the OPTIFAST Program

Participants in the OP group had significantly greater reductions in waist circumference:

- At 26 weeks: -12.0 cm (SD 16.0) vs -7.7 cm (SD 8.3) (OP vs FB, p=0.011)
- At 52 weeks: -11.9 cm (SD 12.1) vs -7.2 cm (SD 9.3) (OP vs FB, p=0.0011)

Participants in the OP group had significantly greater reductions in total amount of body fat lost (measured by DEXA):

- At 26 weeks: -11.3 kg (SD 7.5) vs -4.4 kg (SD 5.9) (OP vs FB, p<0.0001)
- At 52 weeks: -9.7 kg (SD 10.4) vs -3.5 kg (SD 6.6) (OP vs FB, p<0.0001)

No significant difference was observed in discontinuation rates between groups (29.3% OP; 31.9% FB). Main reasons for discontinuation were subject request to no longer participate in the program (11.0% OP; 18.7% FB) or lost to follow-up (11.0% OP; 9.6% FB). 84.5% of the OP group and 68% of the FB group reported at least one adverse event during the year-long trial. The most commonly reported adverse events in the OP group were constipation (18.7%), headache (17.4%), dizziness (16.8%), nasopharyngitis (11.6%), and nausea (11.6%). Serious adverse events were reported by 4.5% (7/155) of the participants in the OPTIFAST group and 3.3% (5/150) in the food-based group; none were assessed by the investigators to be related to treatment.

"The comprehensive OPTIFAST approach combining meal replacement with ongoing medical monitoring and a behavioural intervention, has been proven to support significant weight loss in patients with obesity," noted Dr. Krys Araujo Torres, MD, Head of U.S. Medical Affairs for Nestlé Health Science. "The OPTIWIN study demonstrates this weight loss can be sustained over time and it is an important consideration for individuals looking for weight loss programs that can have a lasting impact on health."

Additional OPTIWIN Results at OBESITYWEEK 2018

Additional results from the OPTIWIN study will be reported at ObesityWeek 2018. Dr. Jamy Ard will present the poster (T-P-3127), titled "OPTIFAST® Increases Weight Loss Response Compared With Food Based Diet Plan: The OPTIWIN Study," on Tuesday, November 13 from 12:00 pm EST to 1:30 pm EST at the Music City Center (Exhibit Hall B-D, Level 3). Dr. Laura Matarese, PhD, RD, will give an oral presentation (T-OR-2018), titled "Effectiveness of OPTIFAST® Compared With Food Based Diet Plan on Body Composition: The OPTIWIN Study," on Tuesday, November 13 at 4:45 pm EST at the Music City Center (Room 201 A-B, Level 2).

About OPTIFAST

The OPTIFAST Program is a non-surgical weight-management option designed for people with a Body Mass Index (BMI) greater than 30. The program, which is available at more than 400 weight loss clinics across the U.S., is a medically-supervised intervention that closely monitors and assesses progress towards better health and emotional well-being. The program utilizes a meal replacement plan that transitions to self-prepared 'everyday' meals, in conjunction with comprehensive patient education and support to help people lose weight, which can in turn reduce weight-related health risks. Clinical supervision is a key component of the program. Patients in the OPTIFAST Program meet regularly with their medical provider for monitoring and counselling.

The OPTIFAST Program was launched in 1976 to fill the growing need to address obesity in a safe and effective way with medical monitoring as a key component. As diseases related to obesity became more prevalent, the OPTIFAST Program was introduced as a sensible option for lifestyle transformation. The OPTIFAST Program is offered by Nestlé Health Science and is available in key markets worldwide. For more information, to see patient stories or to find a weight loss clinic, visit www.optifast.com.

About Nestlé Health Science

Nestlé Health Science, a wholly-owned subsidiary of Nestlé S.A., is a health-science company engaged in advancing the role of nutritional therapy to change the course of health for consumers, patients and its partners in healthcare. Nestlé Health Science's portfolio of nutrition solutions, diagnostics, devices and drugs targets a number of health areas, such as inborn errors of metabolism, pediatric and acute care, obesity care, healthy aging, and gastrointestinal and brain health. It includes brands such as BOOST®, OPTIFAST®, PEPTAMEN®, IMPACT Advanced Recovery®, etc. Through investing in innovation and leveraging leading edge science, Nestlé Health Science brings forward innovative nutritional therapies with proven clinical, health economic value and quality of life benefits. Nestlé Health Science employs approximately 4,400

people worldwide and is headquartered in Epalinges (near Lausanne), Switzerland. For more information, please visit www.nestlehealthscienceus.com

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References

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2 Diabetes Prevention Program Research Group; Knowler WC, Fowler SE, Hamman RF, et al. 10-Year Follow-up of Diabetes Incidence and Weight Loss in the Diabetes Prevention Program Outcomes Study. *Lancet.* 2009; 374: 1677-86.
3 Knowler WC, et al. Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. *N Engl J Med.* 2002; 346: 393-403.
4 Jensen MD, et al. 2013 AHA/ACC/TOS Guideline for the Management of Overweight and Obesity in Adults: a Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines and The Obesity Society. *J Am Coll Cardiol.* 2014; 63(25 Pt B): 2985-3023.