

The OPTIFAST Total and Partial Meal Replacement Program Improves Cardiometabolic Risk in Adults With Obesity – Secondary and Exploratory Analysis of the OPTIWIN Study

O.E. JOHANSEN¹, I.J. NEELAND², A.E. ROTHBERG³, R.J. CHILTON⁴, D. DE LUIS⁵, A.H. HAWKINSON⁶, S.C. COHEN⁷, J.D. ARD⁸

1: Nestlé Health Science, Vevey, Switzerland; 2: University Hospitals Cleveland Medical Center, Cleveland, OH, United States; 3: University of Michigan, Ann Arbor, MI, United States; 4: UTHSCA, San Antonio, TX, United States; 5: Medicine School, Simanacas, Spain; 6: Nestlé Health Science, Bridgewater, NJ, United States; 7: Tox Strategies, Durham, NC, United States; 8: Wake Forest School of Medicine, Winston-Salem, North Carolina, US

INTRODUCTION

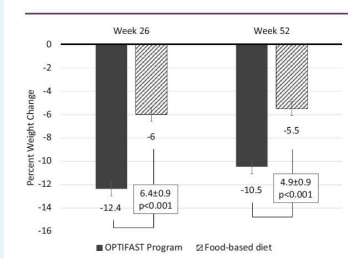
Obesity is a risk factor for the development of cardiovascular disease (CVD) and people with obesity experience CVD events at an earlier age.¹

In the randomized controlled OPTIWIN study³ of 273 individuals (BMI 30-55 kg/m²; age 18 - 70 years), the use of meal replacement products (MRP) with Optifast (OP) compared with a low-calorie food-based (FB) dietary plan, in addition to lifestyle intervention (weekly 45-60-min group behavioral sessions and physical activity), resulted in significant weight loss at week (W) 26 (reduction phase) and W52 (maintenance) (Fig 1).

AIM

We performed secondary and exploratory analysis of the OPTIWIN study to assess effects on CVD risk factors and CVD risk of MRP with OP vs the FB dietary plan during the reduction phase (0-26W) and over the full study period (0-52W).

Fig 1. Weight reduction with OP at W26 & W52²



METHODS

DIETARY INTERVENTIONS

MRP with OP W0-26 – reduction phase

- BMI < 45 kg/m²: 5 MRPs/day (800 kcal total); BMI 45-49.9 kg/m²: 6 MRPs/day (960 kcal); BMI ≥ 50 kg/m²: 6 MRs plus one meal daily of lean protein (3-4 ounces) and one nonstarchy vegetable serving (1100-1200 kcal). Gradual reintroduction of food onwards W12-16 through W26.

MRP with OP W26-52 – maintenance phase

- Calories were gradually increased to achieve weight stability; during this time, participants were advised to use 1-2 MRPs daily.

Low-calorie FB diet W0-26 – reduction phase

- A calorie-restricted diet (fat 25%-30% of total calories) reduced by 500-750 kcal below estimated total energy expenditure (indirect calorimetry plus an activity factor based on self-reported physical activity).

Low-calorie FB diet W26-52 – maintenance phase

- Diet followed a modified version of the Diabetes Prevention Program (DPP).

STATISTICAL ANALYSIS

CV risk factors and CVD risk were analysed as changes over time (mITT) and LS means and LS mean differences calculated.

- Linear mixed model with a subject random intercept effect, fixed intervention effect/visit effect/baseline value effect, a treatment-by-visit interaction term, and confounders (age, race, diabetes status).

Subgroup-analysis were performed for changes in SBP, DBP and ASCVD risk by age at BL, systolic BP at BL and sex.

RESULTS

Baseline characteristics were balanced, the population had a low CV risk (table 1) with the majority <5% 10-year AHA/ACC ASCVD risk.

Table 1. Baseline characteristics; mean (SD) or n (%).

	OP N=135	FB N=138
Age (years)	47.1 (11.2)	47.2 (11.3)
Sex (M/F)	19 (14.1)/116 (85.9)	29 (21.0)/109 (79.0)
BMI (kg/m ²)	38.4 (5.5)	39.2 (6.2)
SBP/DBP (mmHg)	123.4 (13.6)/77.8 (11.6)	125.3 (11.4)/78.0 (10.1)
Total cholesterol (mg/dL)	193.7 (38.6)	187.9 (32.8)
LDL-cholesterol (mg/dL)	122.3 (32.1)	119.7 (30.4)
HDL-cholesterol (mg/dL)	51.7 (13.4)	50.9 (14.0)
Triglycerides (TG) (mg/dL)	135.9 (123.2)	125.8 (63.0)
ASCVD risk score, %	2.6 (3.4)	3.6 (5.1)

CONCLUSIONS

These results support that weight loss induced with MRP using OP, significantly improves CVD risk factors and CVD risk, with the largest magnitude of effect in people > 60 years, and with SBP > 130 mmHg at baseline

REFERENCES

- Khan S.S., et al. Association of body mass index with lifetime risk of cardiovascular disease and compression of morbidity. JAMA Cardiol. 2018;3:280-287
- Ard J.D., et al., Effectiveness of a Total Meal Replacement Program (OPTIFAST Program) on Weight Loss: Results from the OPTIWIN Study. Obesity (Silver Spring), 2019; 27:22-29

RESULTS cont.

Table 2. Effects on CV risk factors and ASCVD risk at W26 (LS mean change (95% CI) from baseline)

	OP, n=116	FB, n=120	Difference (95% CI)
Weight, kg	-13.4 (-15.0, -11.8)	-6.4 (-8.0, -4.9)	-7.0 (-9.2, -4.7)***
SBP, mmHg	-4.87 (-6.63, -3.11)	-1.35 (-3.09, 0.39)	-3.52 (-6.00, -1.03)**
DBP, mmHg	-2.83 (-4.08, -1.57)	-0.26 (-1.50, 0.98)	-2.57 (-4.34, -0.79)**
Total-C, mg/dL	-6.54 (-9.79, -3.29)	-1.82 (-5.01, 1.38)	-4.73 (-9.30, -0.15)*
LDL-C, mg/dL	-5.55 (-8.47, -2.62)	-0.55 (-3.43, 2.33)	-5.00 (-9.12, -0.87)*
HDL-C, mg/dL	4.66 (3.5, 5.81)	1.42 (0.28, 2.56)	3.24 (1.61, 4.87)***
TG, mg/dL	-32.72 (-43.38, -22.06)	-4.69 (-15.18, 5.81)	-28.04 (-43.03, -13.04)***
ASCVD 10-yr risk, %	-0.58 (-0.87, -0.26)	0.07 (-0.22, 0.37)	-0.65 (-1.07, -0.23)**

*p<0.05, **p<0.01, ***p<0.001 vs FB

- A similar, but slightly attenuated pattern was observed at W52

Fig 2. Subgroup effects on systolic blood pressure at W26

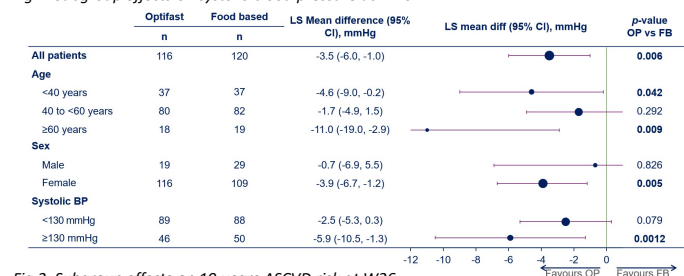
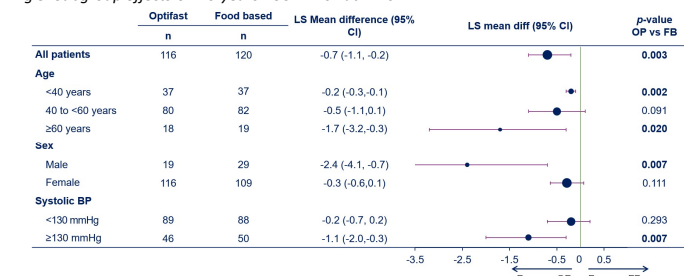


Fig 3. Subgroup effects on 10-years ASCVD risk at W26



- In subgroup analysis by age (<40, 40-59, ≥ 60 years), SBP (</≥ 130 mmHg) and sex, greater treatment effects were generally seen with higher SBP and age, and in men.

ACKNOWLEDGEMENT

We thank all participants and study site personnel involved in this study

CONTACT INFORMATION

Odd Erik Johansen, MD, PhD
Nestlé Health Science
Lausanne, Switzerland
odderik.johansen@nestle.com