Medifast

Clinical Studies Overview

The following abstracts include both peer-reviewed research (consisting of prospective controlled clinical trials and retrospective studies) and in-house clinical data (studies 7 & 8).

The science behind Medifast

The Medifast Program has been helping people lose weight and maintain a healthy lifestyle since 1980. Medifast programs and products were developed by a doctor and have been clinically proven in numerous studies conducted at major university teaching hospitals. Additionally, third-party studies published in leading medical journals have deemed meal replacements to be an effective means of weight loss and weight maintenance. Medifast has been recommended by over 15,000 doctors and used by more than 1 million customers.

Medifast Meals are nutritionally complete, low-calorie, and low-fat—providing everything your body needs to lose weight quickly and safely. Medifast Meals contain a medically designed balance of protein and carbohydrates, as well as 24 essential vitamins and minerals per serving—ensuring your daily nutritional requirements are met while losing weight on the program. Unlike fad diets that restrict a specific macronutrient such as protein or carbohydrates, Medifast is nutritionally balanced—allowing you to maintain lean muscle as you lose weight. This helps you continue to burn fat as you transition, and maintain your weight loss long term.

Most Medifast Meals are formulated with heart-healthy soy protein, which may reduce the risk of heart disease according to some research studies. Soy's naturally occurring isoflavones may also help reduce the risk of bone fractures and osteoporosis. Soy protein is a complete protein—providing all of the essential amino acids. Medifast also manufactures a product line formulated with whey protein, for customers who have an allergy to soy or prefer a non-soy product.

A distinguished scientific advisory board

In September 2008, Medifast announced the formation of its Scientific Advisory Board.

The role of the Board is to continually review the effectiveness, safety, and nutritional benefits of Medifast's products and programs. The team of specialists will also assist in the development of new Meals and supplements, as well as weight-loss approaches for specific medical needs (i.e., patients with heart disease) or lifestyles (vegetarians, etc.).

The work of this cross-disciplinary group builds on Medifast's heritage of medically sound approaches to weight loss, and the incorporation of leading-edge clinical research into the company's products and programs.

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Director of the Johns Hopkins Weight Management Center in Baltimore, MD

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Cardiologist and Assistant Professor at the University of Maryland Medical School

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Functional Foods Expert

Debra L. Miller, Ph.D.

Director of Nutrtion at the Hershey Company

Study 1

REFERENCE	**Haddock CK, Poston WSC, Foreyt JP, DiBartolomeo JJ. "Effectiveness of Medifast supplements combined with obesity pharmacotheraphy: A clinical program evaluation."** ***Eating and Weight Disorders.*** **13:95-101; 2008.**
PURPOSE	To evaluate the long-term impact of Medifast meal-replacement supplements (MMRS) combined with appetite-suppressant medication (ASM) among participants who received 52 weeks of treatment as part of a medically supervised weight-control program.
RESULTS	Participants who completed 52 weeks of treatment experienced substantial weight losses at 12 (-9.4 ± 5.7kg), 24 (-12.0 ± 8.1kg), and 52 weeks (12.4 ± 9.2kg), and all measures were significantly different from baseline weight ($p<0.001$ for all contrasts) for both true completers (n=324) and for ITT analysis (n=1,351). Fifty percent of patients remained in the program at 24 weeks and nearly 25% were still participating at one year. Results were better than those typically reported for obesity pharmacotherapy in both short- and long-term studies, and also better than those reported for partial meal-replacement programs.

This study was published in the June 2008 issue of Eating and Weight Disorders. *Results of this study were presented at the American Society of Bariatric Physicians' annual meeting in May 2007.*

Study 2

REFERENCE	**Davis LM, Coleman CD, Andersen WS, Cheskin LJ. "The effect of metabolism-boosting beverages on 24-hr energy expenditure."** ***The Open Nutrition Journal.*** **2:37-41; 2008.**
PURPOSE	To test the effect of thermogenic meal-replacement beverages (TMRB) containing 90 mg of EGCG and 100 mg of caffeine on resting energy expenditure (REE). Thirty adults (19 women, 11 men) were stratified into 3 groups: lean (n=10, BMI 21.5 ± 2.1); overweight/obese (OW) (n=10, BMI 29.8 ± 2.7); or weight maintainers (WM) (n=10, BMI 28.8 ± 4.0). Following an overnight fast, baseline measurements, including REE via indirect calorimetry, were performed. REE was repeated at 30, 60, 90, and 120 minutes after consuming a TMRB. Appetite was assessed via visual analogue scale at baseline, 30 minutes, and 120 minutes after consuming the TMRB.
RESULTS	Mean 24-hour REE was increased 5.9 ± 2.5% overall ($p=0.000$), 5.7 ± 3.1% among lean subjects ($p=0.0002$), 5.3 ± 1.4% among OW subjects ($p=0.000$), and 6.8 ± 2.7% among WM subjects ($p=0.0007$). Appetite was significantly reduced 30 minutes after consuming the TMRB ($p=0.0002$). TMRBs appear to be a promising weight-control tool.

This study was presented as a poster session at Experimental Biology, 2008.

Study 3

REFERENCE	**Cheskin LJ, *et al.* "Efficacy of meal replacements versus a standard food-based diet for weight loss in type 2 diabetes." *The Diabetes Educator.* 34(1):118-127; Jan/Feb 2008.**
PURPOSE	To compare the efficacy of a portion-controlled meal-replacement diet (PCD) to a standard diet (SD) (based on recommendations by the American Diabetes Association) in achieving and maintaining weight loss among 119 obese men and women with type 2 diabetes mellitus.
RESULTS	Using intention-to-treat analyses, weight loss at 34 weeks and weight maintenance at 86 weeks was significantly better on PCD versus SD. Approximately 40% of the PCD participants lost >5% of their initial weight compared with 12% of those on the SD. Significant improvements in biochemical and metabolic measures were observed at 34 weeks in both groups. The retention rate and self-reported ease of adherence in the PCD group were significantly higher throughout the study.

This study was published in the January/February 2008 issue of The Diabetes Educator. *The peer-reviewed journal is the official journal of the American Association of Diabetes Educators. The study was also presented at the American Diabetes Association's 65th Annual Scientific Session, 2005.*

Study 4

REFERENCE	**Cheskin LJ, *et al.* "A RCT comparing balanced energy deficit diets with or without meal replacements for weight loss and maintenance among children dieting alone or with a parent." Johns Hopkins Bloomberg School of Public Health, Center for Human Nutrition, Department of International Health.**
PURPOSE	To compare the safety and efficacy of supplemental Medifast portion-controlled meal replacements (MRs) to a USDA Food Guide Pyramid-based diet. Both weight-loss diets were 20% energy-restricted (~500 kcal deficit). Eighty children (8-15 y.o.), BMI≥95th%ile, were screened and randomized to either a MR diet (3 MRs/d during active weight loss and 2 MRs/d during maintenance) or to the food-based diet. Subjects were further randomized to dieting alone or with a parent.
RESULTS	By ITT analysis, dieting alone vs. with a parent or food vs. MR made no difference in weight outcome. However, following initial weight loss (6 mos) and 1 yr maintenance (18 mos), significant benefits were seen in the MR group in BMI%ile (0 mos=98.8 ± 1.0, 6 mos=96.6 ± 3.2, 18 mos=96.4 ± 3.4); body fat (↓5.9% @ 6 mos, 5.3% @ 18 mos); total cholesterol (↓6.7% @ 6 mos, 5.6% @ 18 mos); LDL (↓19.8% @ 6 mos, 7.9% @ 18 mos); and triglycerides (↓23.6% @ 6 mos, 22.3% @ 18 mos). No significant between-group differences, differences in growth rates, or adverse events were observed. Conclusions: Among overweight 8-15 y.o. children, dieting with or without a parent, meal replacements were as safe and effective as a food-based diet for weight loss and maintenance.

This study was presented as a poster session at Experimental Biology, 2007.

Study 5

REFERENCE	**Tchernof A, Starling R, Turner A, *et al*. "Impaired capacity to lose visceral adipose tissue during weight reduction in obese postmenopausal women with the Trp64Arg B3-adrenoceptor gene variant." *Diabetes.* 49:1709-1713; 2000.**
PURPOSE	To examine the effect of the Trp64Arg gene variant on total and visceral adipose tissue loss, and cardiovascular risk factors in response to weight reduction among 24 obese women (age 57 ± 4 yrs) in a 13 ± 3 mos weight reduction program of 1,200 kcal with or without the inclusion of Medifast.
RESULTS	Whether women were carriers or noncarriers of the Trp64Arg allele, significant weight loss (-16.4 ± 5.0kg vs. -14.1 ± 6.2kg, NS) and reductions in body fat (-10.0 ± 5.2 vs. -11.5 ± 3.9kg, NS) were observed in response to a calorie-restricted program with or without Medifast. Loss of visceral adipose tissue was 43% lower in carriers of the Trp64Arg allele compared with noncarriers (-46 ± 27 vs. -81 ± 51cm^2, p=0.05). The study concluded that older women carrying the Trp64Arg B3-adrenoceptor gene variant have an impaired capacity to lose visceral adipose tissue in response to a calorie-restricted diet.

Study 6

REFERENCE	**Matalon V. "An evaluation of weight loss following a carbohydrate and fat restricted diet with appetite suppressant and dietary supplementation." *The Bariatrician.* 10-13; 2000.**
PURPOSE	To assess the safety and effectiveness of a weight-loss regimen consisting of a carbohydrate- and fat-restricted diet supplemented with an appetite suppressant, a dietary supplement, and a liquid protein drink (Medifast) in an open label trial. Baseline and 6-mos evaluations of body weight (lbs), body fat (%), BMI (kg/m^2), lean body mass, water weight, and blood pressure were performed. At 6 mos, statistically significant differences were found for body weight ($p<0.001$), percent body fat ($p<0.001$), BMI ($p<0.001$), lean body mass ($p<0.001$), water weight ($p=0.01$), and body systolic ($p=0.003$) and diastolic ($p<0.001$) blood pressure.
RESULTS	Of 47 patients enrolled, 24 (51%) completed six months using the dietary regimen prescribed. Data was analyzed for all patients who were treated with the diet, as well as for the subset of patients who completed the entire study period. The dietary regimen showed that a carbohydrate- and fat-restricted program supplemented by a natural appetite suppressant can lead to progressive weight loss of comparable value to prescribed pharmacologic agents at the time of study. Patients in the study experienced statistically significant decreases in overall body weight, percent body fat, BMI, lean body mass, total body water, and both systolic and diastolic blood pressure.

Study 7

REFERENCE	**Crowell MD, Cheskin LJ. "Multicenter evaluation of health benefits and weight loss on the Medifast weight management program." The Johns Hopkins University School of Medicine.**
PURPOSE	To retrospectively evaluate the efficacy of a medically supervised, protein-supplemented modified program (Medifast) for weight reduction and to evaluate the impact of weight reduction on coexisting health problems.
RESULTS	The results of the study concluded that medically supervised, protein-sparing meal-replacement programs offer a safe and effective means of weight reduction and are accompanied by significant improvements in coexisting health problems. Of samples taken, males lost an average of 67 lbs and females lost an average of 47 lbs during fasting. The study found significant reductions in total cholesterol and triglycerides, systolic and diastolic blood pressure, and normalized blood pressure in hypertensive patients.

A statistical review of patient charts, unpublished data on file. 1991.

Study 8

REFERENCE	**Davis LM, Cheskin LJ. "Dietary intervention using Medifast meal replacements in pre-bariatric surgery patients." Johns Hopkins Weight Management Center; 2006.**
PURPOSE	N=14 severely obese patients—13 females (11 African Americans, 2 Caucasians) and 1 male (Caucasian)—with a mean BMI of 64.14 kg/m2 (range 40.2kg/m2 to 91.7kg/m2) entered a 6-month weight-control program at the Johns Hopkins Weight Management Center. All patients were Medicaid (Priority Partners) recipients. The program provided a comprehensive approach to weight control focused on diet, behavior, and physical activity. Portion-controlled meal replacements (MRs) supplied by Medifast were utilized as part of the dietary-behavior intervention. All subjects met with a licensed dietitian and were prescribed a 1,000-1,200 kcal/day diet plan incorporating up to 6 MRs/day. Only 1 subject chose not to incorporate meal replacements as part of a low-calorie diet plan. The average intake of meal replacements was 2.5-3 per day through the duration of the study.
RESULTS	After 6 months on the program, patients lost an average of 26.73 lbs (-2.86kg/m2) and 6.96% body weight, and reported a high level of satisfaction with their diet plan. Program completers at 1 month were N=13, at 3 months N=12, and 6 months N=10.

A statistical review of patient charts, unpublished data on file. 2006.

Study 9

REFERENCE

Coleman CD, Davis LM, Rampolla J, Kiel J, Hutchisen T, Ford L, Andersen WS. "Efficacy of Medifast's 5 & 1 meal replacement program compared to a food-based diet for weight loss and weight maintenance: 4-month weight loss results."

PURPOSE

To determine the effectiveness of Medifast's 5 & 1 Plan on body weight and body composition compared to an isocaloric food-cased diet plan for a 4-month period of weight loss.

METHODS

Ninety obese adults were randomly assigned to 2 groups: Medifast (MD) (n=45; 30 women, 15 men; BMI 38.5 ± 6.8) and Food-based (FB) (n=45; 34 women, 11 men; BMI 37.8 ± 4.5). Subjects met biweekly with Registered Dietitians to have anthropometrics measured and for dietary and behavioral counseling. Weight and BP were measured biweekly. Waist circumference (WC), % body fat, lean muscle mass (LMM), visceral fat, and pulse were measured every 4 weeks.

RESULTS

Subjects lost 2 times more body weight on Medifast [MD -29.8lbs, FB -14.4lbs (p=0.000); % wt loss: MD -12.3, FB -6.7 (p=0.002)]; 5 times more body fat [% Δ in body fat: MD -13.6, FB -2.7 (p=0.001)]; improved WC [WC Δ: MD -13cm, FB -8.2cm (p=0.047); % Δ WC: MD -11.2, FB -7.2 (p=0.069)]; and had 7 times greater % reduction in visceral fat: MD -25.4, FB -3.7 (p=0.001), while maintaining LMM [% wt loss as LMM: MD 18.1, FB 42.3 (p=0.01)]. No significant between groups differences were found for BP or pulse. Retention rates (64% vs. 44%) and program adherence was higher in the MD group.

CONCLUSION: At 4 months, Medifast's 5 & 1 Plan out-performed an isocaloric food-based diet in weight loss and body composition. This research was funded by Medifast, Inc., Owings Mills, MD.

This abstract was presented under peer review at Experimental Biology in April 2009.

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