



## Clinical Studies Overview





The Science Behind Medifast®: A Foundation for Better Health ..... 2

A Distinguished Scientific Advisory Board ..... 3

Medifast Clinical Research Studies

The 5 & 1 Plan®

    Arterburn (2019) ..... 4

    Shikany (2013) ..... 5

    Coleman (2012) ..... 6

    Davis (2010) ..... 7

The 4 & 2 & 1 Plan®

    Beavers (2018) ..... 8

    Normandin (2018) ..... 9

    Coleman (2015) ..... 10

The 5 & 2 & 2 Plan®

    Kiel (2015) ..... 11

Diabetes

    Coleman (2017) ..... 12

    Cheskin (2008) ..... 13

Polycystic Ovarian Syndrome (PCOS) (Yuh, 2011) ..... 14

Seniors

    Serra (2019) ..... 15

    Weaver (2019) ..... 16

    Beavers (2018) ..... 17

    Shaver (2018) ..... 18

    Normandin (2018) ..... 19

    Kelleher (2017) ..... 20

    Beavers (2015) ..... 21

Teenagers (Cheskin, 2007) ..... 22

Trp64Arg Gene Variant (Tchernof, 2000) ..... 23

Obesity Pharmacotherapy and Non-Pharmaceutical Appetite Suppressants

    Moldovan (2016) ..... 24

    Haddock (2008) ..... 25

    Matalon (2000) ..... 26

Medifast Products (Davis, 2008) ..... 27

References ..... 28

## THE SCIENCE BEHIND MEDIFAST®: A FOUNDATION FOR BETTER HEALTH

Obesity is considered one of the most pressing health issues of our time.<sup>1</sup> Over 70% of adults in the United States (US) are overweight or obese, with nearly 40% having obesity.<sup>2,5</sup> Being overweight or obese increases the risk of developing many related, often serious conditions (e.g. heart disease, stroke, diabetes, and even some forms of cancer) and has a substantial economic impact.<sup>1,6,7</sup> The US spends an estimated \$190 billion on obesity-related medical conditions, and the average annual medical costs for those with obesity are over \$1,400 higher compared to people in a normal weight range.<sup>8,9</sup> Other countries are also experiencing growing rates of obesity and, worldwide, obesity has nearly tripled since 1975.<sup>10</sup> Weight loss can help to reduce both the medical and economic impact of obesity by decreasing the risk of developing associated chronic diseases.<sup>6,11-16</sup> Unfortunately, while there are many options available for managing weight, not all are healthy, safe, or effective.

The long-standing scientific foundation and clinical heritage of Medifast is what makes our Company so unique. Originally developed by a physician, Medifast leverages diverse brand offerings, such as the **OPTAVIA**® Fuelings (meal replacements), combined with the dynamism and support of an **OPTAVIA** Coach for a comprehensive approach to Lifelong Transformation One Healthy Habit at a Time®. All of our programs feature a combination of Medifast/**OPTAVIA** meal replacements, conventional food choices, easy-to-understand meal plans, and customizable levels of support for weight loss and weight maintenance—all backed by our team of registered dietitian nutritionists, behavioral experts, and food scientists.

Our inclusive approach to weight management aligns well with the guidelines for the management of overweight and obesity issued by the American Heart Association, the American College of Cardiology and



The Obesity Society. These guidelines recommend individuals who are currently at an unhealthy weight (overweight or obese) participate in a comprehensive lifestyle program which includes a reduced calorie diet, exercise, and support that promotes positive behavioral changes, as the cornerstone of all treatment options, with the goal of achieving clinically meaningful weight loss of at least 5-10% within a 6-month period.<sup>6</sup> These guidelines also support the use of commercial weight loss programs as an option for weight loss, provided they are backed by evidence of their safety and efficacy and offer a comprehensive lifestyle intervention.<sup>6</sup>

Research also supports the use of meal replacements as a safe and effective tool for limiting calorie intake and promoting weight loss and maintenance among individuals who are overweight or obese.<sup>17-24</sup> Similarly, the Medifast/**OPTAVIA** meal replacements serve as a convenient, individually-portioned, calorie-controlled source of nutrition. These tasty offerings are at the heart of Medifast's clinically proven programs, helping individuals manage their weight quickly, safely, and simply.

We invite you to read this Clinical Studies Overview, a compilation of abstracts from peer-reviewed clinical research of randomized, controlled trials, prospective, and retrospective studies that support the use of our products and programs in a wide variety of populations. All studies were conducted in the US. Not all of the programs studied are available in all international markets.

The Medifast Scientific Advisory Board is comprised of internationally-recognized experts, all of whom have made significant contributions in their respective field. The function of the Scientific Advisory Board is to provide objective insight and external expertise to help guide Medifast in making informed, evidence-based decisions on medical, nutritional, and scientific matters. The Scientific Advisory Board serves as a part of our foundation to create scientifically-valid, consumer-centric, high-quality innovations for lasting health.

This cross-disciplinary group consists of distinguished physicians, dietitians, academic researchers, and health-related policy experts. The work of this prestigious board builds on Medifast’s scientific and clinical heritage, which focuses on sound approaches to weight management while exploring forward-looking ingredients, offerings, and clinical research opportunities.

Medifast first formed their Scientific Advisory Board in 2008. As of June 2019, the Medifast Scientific Advisory Board is comprised of the following experts (left to right):



**George Bray, MD**  
Boyd Professor Emeritus,  
Pennington Biomedical  
Research Center, Louisiana State  
University

**Sylvia B. Rowe**  
President, SR Strategy and  
Adjunct Professor at Tufts  
Friedman School of Nutrition  
Science and Policy and  
University of Massachusetts,  
Amherst

**Carsten Smidt, PhD**  
Owner, Smidt Labs, Inc.  
and Fellow, American  
College of Nutrition

**Susan Barr, PhD**  
Professor Emerita, Food  
Nutrition and Health,  
University of British Columbia

**Mark Messina, PhD**  
Co-owner, Nutrition Matters,  
Inc., Executive Director, the Soy  
Nutrition Institute, and Adjunct  
Associate Professor, Loma Linda  
University

**Steven Heymsfield, MD**  
Professor and Director,  
Metabolism & Body  
Composition Laboratory,  
Pennington Biomedical  
Research Center, Louisiana State  
University

## Arterburn (2019)

### Randomized Controlled Trial Assessing Two Commercial Weight Loss Programs in Adults with Overweight or Obesity

LM Arterburn<sup>1</sup>, CD Coleman<sup>1</sup>, J Kiel<sup>1</sup>, K Kelley<sup>2</sup>, L Mantilla<sup>2</sup>, N Frye<sup>1</sup>, K Sanoshy<sup>2</sup>, CM Cook<sup>2</sup>

<sup>1</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., Baltimore, Maryland, USA; <sup>2</sup>Biofortis, Mérieux NutriSciences, Addison, IL, USA

#### PURPOSE/OBJECTIVE:

Lifestyle interventions remain the cornerstone for obesity treatment. Commercial programs offer one weight loss approach, yet the efficacy of few such programs have been rigorously investigated. The purpose of this study was to evaluate the efficacy of two commercial weight-loss programs, both utilizing pre-portioned meal replacements (MRs) and different levels of behavioral support, compared to a self-directed control diet in adults with overweight and obesity.

#### METHODS/DESIGN:

In this 16-week study, participants were randomized to the low-calorie **OPTAVIA**® 5 & 1 Plan® with telephone coaching (OPT), the reduced-calorie Medifast® 4 & 2 & 1 self-guided plan (MED), or a self-directed, reduced-calorie control diet. Differences in weight, body composition (DXA) and body circumferences, all measured monthly, were assessed by analysis of covariance with sex and baseline measures as covariates.

#### RESULTS:

Of 198 participants randomized (80.8% female, BMI 34.2 kg/m<sup>2</sup>, 45.7 years), 92.3% completed the study. The OPT and MED groups had significantly greater reductions in body weight (-5.7% and -5.0%, respectively, p<0.0001), fat and abdominal fat mass (p<0.0001) and waist and hip circumferences (p≤0.003) than control at 16 weeks. Weight change was correlated with MR usage and completion of coaching support calls.

#### CONCLUSIONS:

Both structured commercial programs were more efficacious than a self-directed, reduced-calorie diet for weight loss and other anthropometric measures. Evidence-based commercial programs can be an important tool to help adults with overweight and obesity lose clinically relevant amounts of weight.

#### REFERENCE:

Arterburn L.M., Coleman C.D., Kiel J., Kelley K., Mantilla L., Frye N., Sanoshy K., Cook C.M. (2019). Randomized Controlled Trial Assessing Two Commercial Weight Loss Programs in Adults with Overweight or Obesity. *Obes Sci Pract*, 5(1):3-14 doi: [doi.org/10.1002/osp4.312](https://doi.org/10.1002/osp4.312)

Shikany (2013)

## Randomized Controlled Trial of the Medifast 5 & 1 Plan for Weight loss

JM Shikany<sup>1,2</sup>, AS Thomas<sup>1</sup>, TM Beasley<sup>3</sup>, CE Lewis<sup>1,2</sup>, DB Allison<sup>2,4</sup>

<sup>1</sup>Division of Preventive Medicine, School of Medicine, University of Alabama at Birmingham, Birmingham, AL, USA; <sup>2</sup>Nutrition Obesity Research Center, University of Alabama at Birmingham, Birmingham, AL, USA; <sup>3</sup>Department of Biostatistics, School of Public Health, University of Alabama at Birmingham, Birmingham, AL, USA; <sup>4</sup>Dean's Office, School of Public Health, University of Alabama at Birmingham, Birmingham, AL, USA.

### PURPOSE/OBJECTIVE:

The Medifast 5 & 1 Plan (MD) is a portion-controlled, nutritionally-balanced, low-fat weight-loss plan. We studied the effects of MD compared with a reduced-energy, food-based diet (FB) on body weight, waist circumference, fat mass and other measures in adults.

### METHODS/DESIGN:

We conducted a two-parallel-arm, randomized, controlled trial comparing MD to FB over 52 weeks. A total of 120 men and women aged 19–65 years with BMI  $\geq 35$  and  $\leq 50$  kg/m<sup>2</sup> were randomized to MD (n=60) or FB (n=60). Follow-up included a 26-week weight-loss phase and 26-week weight-maintenance phase. Anthropometric, body composition, biochemical and appetite/satiety measures were performed at baseline and at 26 and 52 weeks. An intention-to-treat, linear mixed models analysis was the primary analysis.

### RESULTS:

Fifty MD subjects (83.3%) and 45 FB subjects (75.0%) completed the study on assigned treatment. At 26 weeks, race-adjusted mean weight loss was 7.5kg in MD subjects vs 3.8kg in FB subjects (p=0.0002 for difference); reduction in waist circumference was 5.7cm in MD vs 3.7cm in FB (p=0.0064); and fat mass loss was 6.4kg in MD vs 3.7kg in FB (p=0.0011). At 52 weeks, the corresponding reductions were 4.7 vs 1.9kg (p=0.0004); 5.0 vs 3.6 cm (p=0.0082); and 4.1 vs 1.9kg (p=0.0019) in MD and FB subjects, respectively.

### CONCLUSIONS:

In obese adults, MD resulted in significantly greater reductions in body weight and fat compared with a FB diet for 1 year after randomization.

### REFERENCE:

Shikany J.M., Thomas A.S., Beasley T.M., Lewis C.E., Allison D.B. (2013). Randomized Controlled Trial of the Medifast 5 & 1 Plan for Weight Loss. *Int J Obes* (Lond), 37(12), 1571-1578. doi: [10.1038/ijo.2013.43](https://doi.org/10.1038/ijo.2013.43).

Coleman (2012)

## Use of the Medifast Meal Replacement Program for Weight Loss in Overweight and Obese Clients: A Retrospective Chart Review of Three Medifast Weight Control Centers (MWCC)

C Coleman<sup>1</sup>, J Kiel<sup>1</sup>, A Hanlon-Mitola<sup>2</sup>, C Sonzone<sup>1</sup>, N Fuller<sup>1</sup>, LM Davis<sup>1</sup><sup>1</sup>Medifast, Inc., Owings Mills, Maryland, USA; <sup>2</sup>Private Practice, Clifton Park, New York, USA.

### PURPOSE/OBJECTIVE:

A chart review was performed to evaluate the effectiveness of the Medifast (MD) meal replacement (MR) plan in a Medifast Weight Control Center (MWCC) on body weight, body composition, and other health measures at 4, 12, 24 weeks, and final weight loss visit.

### METHODS/DESIGN:

Charts included adults aged 18-70 (n=446) with a BMI  $\geq$  25 kg/m<sup>2</sup> who attended one of three MWCCs and were following the MD MR program. Data were collected electronically and included weight, systolic and diastolic blood pressure, pulse, lean muscle mass (LMM), body fat mass, % body fat, and abdominal circumference. Compliance measures included attendance at weekly visits, intake of MRs and supplements, food journals, and ketone testing.

### RESULTS:

Significant weight loss and % weight loss were achieved at all time points with clinically significant weight loss (>5%) occurring in just 4 weeks. Additionally, significant improvements in body composition were seen at all time points coupled with increases in % total body weight as LMM (% LMM improved by 3.5, 9.8, 16.0, and 13.9%, respectively). Blood pressure and pulse were significantly improved, demonstrating the clinical benefit for clients. Multivariate regression revealed a strong inverse relationship between weight change, % compliance with attendance, and the number of weeks that MRs were taken as recommended as well as a positive association with number of ketone tests.

### CONCLUSIONS:

The MD MR plan, combined with the support and accountability available in the MWCC, is an efficacious program that promotes significant weight loss and improvements in body composition. These results reveal significant associations between components of compliance and weight loss, but particularly highlight the importance of attendance, a focus of the MWCC model compared to non-clinic models.

### REFERENCE:

Coleman C., Kiel J., Hanlon-Mitola A., Sonzone C., Fuller N., Davis L.M. (2012). Use of the Medifast Meal Replacement Program for Weight Loss in Overweight and Obese Clients: A Retrospective Chart Review of Three Medifast Weight Control Centers (MWCC). *Food and Nutrition Sciences*, 03(10), 1433-1444. doi: <http://dx.doi.org/10.4236/fns.2012.310187>.



Davis (2010)

## Efficacy of a Meal Replacement Diet Plan Compared to a Food-based Diet Plan After a Period of Weight Loss and Weight Maintenance: A Randomized Controlled Trial

LM Davis<sup>1</sup>, C Coleman<sup>1</sup>, J Kiel<sup>1</sup>, J Rampolla<sup>1</sup>, T Hutchisen<sup>1</sup>, L Ford<sup>1</sup>, WS Andersen<sup>1</sup>, A Hanlon-Mitola<sup>2</sup>

<sup>1</sup>Research & Development, Medifast, Inc., Owings Mills, Maryland, USA; <sup>2</sup>Private Practice, Clifton Park, New York, USA.

### PURPOSE/OBJECTIVE:

Obesity has reached epidemic proportions in the United States. It is implicated in the development of a variety of chronic disease states and is associated with increased levels of inflammation and oxidative stress.

The objective of this study is to examine the effect of Medifast's meal replacement program (MD) on body weight, body composition, and biomarkers of inflammation and oxidative stress among obese individuals following a period of weight loss and weight maintenance compared to a an isocaloric, food-based diet (FB).

### METHODS/DESIGN:

This 40-week randomized, controlled clinical trial included 90 obese adults with a body mass index (BMI) between 30 and 50 kg/m<sup>2</sup>, randomly assigned to one of two weight loss programs for 16 weeks and then followed for a 24-week period of weight maintenance. The dietary interventions consisted of Medifast's meal replacement program for weight loss and weight maintenance, or a self-selected isocaloric, food-based meal plan.

### RESULTS:

Weight loss at 16 weeks was significantly better in the Medifast group (MD) versus the food-based group (FB) (12.3% vs. 6.7%), and while significantly more weight was regained during weight maintenance on MD versus FB, overall greater weight loss was achieved on MD versus FB. Significantly more of the MD participants lost ≥5% of their initial weight at week 16 (93% vs. 55%) and week 40 (62% vs. 30%). There was no difference in satiety observed between the two groups during the weight loss phase. Significant improvements in body composition were also observed in MD participants compared to FB at week 16 and week 40. At week 40, both groups experienced improvements in biochemical outcomes and other clinical indicators.

### CONCLUSIONS:

Our data suggest that the meal replacement diet plan evaluated was an effective strategy for producing robust initial weight loss and for achieving improvements in a number of health-related parameters during weight maintenance, including inflammation and oxidative stress, two key factors more recently shown to underlie our most common chronic diseases.

### REFERENCE:

Davis L.M., Coleman C., Kiel J., Rampolla J., Hutchisen T., Ford L., Andersen W., Hanlon-Mitola A. (2010). Efficacy of a Meal Replacement Diet Plan Compared to a Food-based Diet Plan After a Period of Weight Loss and Weight Maintenance: A Randomized Controlled Trial. *Nutr J*, 9(1). doi: [10.1186/1475-2891-9-11](https://doi.org/10.1186/1475-2891-9-11).

## Beavers (2018)

### Effect of an Energy-Restricted, Nutritionally Complete, Higher Protein Meal Plan on Body Composition and Mobility in Older Adults with Obesity: A Randomized Controlled Trial

KM Beavers<sup>1</sup>, BA Nesbit<sup>1</sup>, JR Kiel<sup>2</sup>, JL Sheedy<sup>1</sup>, LM Arterburn<sup>2</sup>, AE Collins<sup>1</sup>, SA Ford<sup>1</sup>, RM Henderson<sup>3</sup>, CD Coleman<sup>2</sup>, DP Beavers<sup>4</sup>

<sup>1</sup>Department of Health and Exercise Science, Wake Forest University, Winston-Salem, North Carolina; <sup>2</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., Baltimore, Maryland; <sup>3</sup>Department of Internal Medicine, Section on Gerontology and Geriatric Medicine, Winston-Salem, North Carolina; <sup>4</sup>Department of Biostatistical Sciences, Wake Forest School of Medicine, Winston-Salem, North Carolina.

#### PURPOSE/OBJECTIVE:

Increasing protein content of the diet might be an effective strategy to preserve muscle mass in older adults undergoing caloric restriction, thereby preserving muscle function.

#### METHODS/DESIGN:

Ninety-six older adults (70 ± 3.7 years, 74% women, 27% African American) with obesity (35.4 ± 3.3 kg/m<sup>2</sup>; 47% total body fat) were randomized to a 6-month higher protein (providing 1.2-1.5 g/kg/d) weight loss (WL) program, utilizing the Medifast 4 & 2 & 1 Plan, or to weight stability (WS). Dual-energy x-ray absorptiometry-acquired total body mass and composition, and fast gait speed over 400 m was assessed at baseline, 3, and 6 months.

#### RESULTS:

At baseline, dual-energy x-ray absorptiometry-acquired total body, fat, and lean masses were 95.9 ± 14.6, 44.6 ± 7.6, and 48.7 ± 9.5 kg, respectively, and 400-m gait speed was 1.17 ± 0.20 m/s. Total body mass was significantly reduced in the WL group (-8.17 [-9.56, -6.77] kg) compared to the WS group (-1.16 [-2.59, 0.27] kg), with 87% of total mass lost as fat (WL: -7.1 [-8.1, -6.1] kg; -15.9% change from baseline). A differential treatment effect was not observed for change in lean mass (WL: -0.81 [-1.40, -0.23] kg vs WS: -0.24 [-0.85, 0.36] kg). Four-hundred-meter gait speed was also unchanged from baseline although trends suggest slightly increased gait speed in the WL group [0.01 (-0.02, 0.04) m/s] compared with the WS group [-0.02 (-0.05, 0.01) m/s].

#### CONCLUSIONS:

Intentional weight loss using a high-protein diet is effective in producing significant total body mass and fat mass loss, while helping preserve lean body mass and mobility, in relatively high-functioning older adults with obesity.

#### REFERENCE:

Beavers K.M., Nesbit B.A., Kiel J.R., Sheedy J.L., Arterburn L.M., Collins A.E., Ford S.A., Henderson R.M., Coleman C.D., Beavers D.P. (2018) Effect of an Energy Restricted, Nutritionally Complete, Higher Protein Meal Plan on Body Composition and Mobility in Older Adults with Obesity: A Randomized Controlled Trial. *J Gerontol A Bio Sci Med Sci*. doi: [10.1093/gerona/gly146](https://doi.org/10.1093/gerona/gly146).

Normandin (2018)

## Feasibility of Weighted Vest Use During a Dietary Weight Loss Intervention and Effects on Body Composition and Physical Function in Older Adults

E Normandin<sup>1</sup>, D Yow<sup>1</sup>, C Crotts<sup>1</sup>, J Kiel<sup>2</sup>, KM Beavers<sup>3</sup>, BJ Nicklas<sup>1,3</sup>

<sup>1</sup>Section on Gerontology and Geriatric Medicine, Wake Forest School of Medicine, Winston-Salem, NC 27157, USA; <sup>2</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., Baltimore, MD 21202, USA; <sup>3</sup>Department of Health and Exercise Science, Wake Forest University, Winston-Salem, NC 27109, USA.

### PURPOSE/OBJECTIVE:

While intentional weight loss in older adults with obesity yields clinically important health benefits there is a need to minimize the negative effects of weight loss on concomitant loss of muscle mass and strength. Data show wearing weighted vests during exercise improves lean mass and lower extremity strength, however the efficacy of wearing a weighted vest during a period of weight loss to mitigate muscle and strength loss is not known.

This study examined the feasibility of daily weighted vest use during a dietary weight loss intervention, and examined effects of vest use on body composition and physical function in well-functioning older adults with obesity.

### METHODS/DESIGN:

*Design:* Randomized, controlled pilot study. *Setting:* Wake Forest Baptist Medical Center in Winston-Salem, NC. *Participants:* 37 older (age = 65-79 years), obese (BMI=30-40 kg/m<sup>2</sup>) sedentary men and women. *Interventions:* 22-week behavioral diet intervention (targeting 10% weight loss, 1100-1300 kcals/day) with (Diet+Vest; n=20) or without (Diet; n=17) weighted vest use (goal of 10 hours/day with weight added weekly according to individual loss of body mass). *Measurements:* Body composition by dual-energy x-ray absorptiometry and measures of physical function, mobility, and muscle strength/power.

### RESULTS:

Average weighted vest use was 6.7 ± 2.2 hours/day and the vest-wear goal of 10 hrs/day was achieved for 67 ± 22% of total intervention days. Five participants reported adverse events from wearing the vest (all back pain or soreness). Both groups lost a similar amount of weight (Diet= -11.2 ± 4.4 kg; Diet+Vest= -11.0 ± 6.3 kg; p<0.001), with no differences between groups (p=0.25). Fat mass, lean mass, and % body fat decreased significantly (p<0.0001), with no differences between groups. Compared to Diet+Vest, the Diet intervention resulted in greater decreases in leg power (p<0.02), with no other between group differences in physical function.

### CONCLUSIONS:

This pilot study showed that vest use during dietary weight loss is feasible and safe in well-functioning older adults with obesity. Larger studies are needed to definitively determine whether external replacement of lost weight during caloric restriction may preserve lower extremity muscle strength and power.

### REFERENCE:

Normandin E., Yow D., Crotts C., Kiel J., Beavers K.M., Nicklas B.J. (2018). Feasibility of Weighted Vest Use During a Dietary Weight Loss Intervention and Effects on Body Composition and Physical Function in Older Adults. *J of Frailty & Aging*, 7(3):198-203. doi: [10.14283/jfa.2018.17](https://doi.org/10.14283/jfa.2018.17); [PMC6489119](https://pubmed.ncbi.nlm.nih.gov/36489119/).

Coleman (2015)

## Effectiveness of a Medifast Meal Replacement Plan on Weight, Body Composition, and Cardiometabolic Risk Factors in Overweight and Obese Adults: A Multicenter Systematic Retrospective Chart Review Study

CD Coleman<sup>1</sup>, JR Kiel<sup>1</sup>, AH Mitola<sup>2</sup>, JS Langford<sup>1</sup>, KN Davis<sup>1</sup>, LM Arterburn<sup>1</sup><sup>1</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., 11445 Cronridge Drive, Owings Mills, MD, United States and <sup>2</sup>Independent Consultant, Clifton Park, NY, United States.

### PURPOSE/OBJECTIVE:

Recent medical guidelines emphasize the importance of actively treating overweight and obesity with diet and lifestyle intervention to achieve  $\geq 5\%$  weight loss in a 6-month period. Commercial programs offer one approach provided there is evidence of their efficacy and safety. This study was conducted to evaluate the effectiveness of the Medifast® 4 & 2 & 1 Plan™ on weight loss, body composition and cardiometabolic risk factors in overweight and obese adults.

### METHODS/DESIGN:

A systematic retrospective chart review of 310 overweight and obese clients following the Medifast 4 & 2 & 1 Plan at one of 21 Medifast Weight Control Centers® was conducted. Data were recorded electronically and key data points were independently verified. The primary endpoint was change from baseline body weight at 12 weeks. Within group paired t-tests were used to examine changes from baseline in a completers population. Differences between gender and age subgroups were examined using bivariate t-tests and mixed model regression analyses.

### RESULTS:

For the primary endpoint at 12 weeks, body weight among completers (n=185) was reduced by a mean of  $10.9 \pm 5.6$  kg (-10.1%,  $p < 0.0001$ ), and at 24 weeks (n=81) mean weight was reduced by  $16.0 \pm 7.9$  kg (-14.3 %). At 12 and 24 weeks, 85% and 96% of those remaining on the plan, respectively, had lost  $\geq 5\%$  of their baseline body weight. Lean mass was preserved to within 5% of baseline throughout the 24 weeks, and fat mass represented  $\geq 80\%$  of the body weight lost from 12 weeks onward. Men, women, seniors ( $\geq 65$  yrs), and non-seniors ( $< 65$  yrs) all had significant weight reductions with preservation of lean mass. Significant improvements in blood pressure, pulse and waist-to-hip ratio were observed. Mean weight regain among the subset who entered a formal maintenance phase was  $< 2\%$  during an average follow-up of 34 weeks. The meal plan was well tolerated, and program adherence was  $> 85\%$ .

### CONCLUSIONS:

The 4 & 2 & 1 Plan used at Medifast Weight Control Centers was effective for weight loss, preservation of lean mass and improvement in cardiometabolic risk factors. The plan was generally well tolerated in a broad population of overweight and obese adults. #NCT02150837.

### REFERENCE:

Coleman C.D., Kiel J.R., Mitola A.H., Langford J.S., Davis K.N., Arterburn L.M. (2015) Effectiveness of a Medifast Meal Replacement Program on Weight, Body Composition and Cardiometabolic Risk Factors in Overweight and Obese Adults: A Multicenter Systematic Retrospective Chart Review Study. *Nutr J*, 14, 77. doi: [10.1186/s12937-015-0062-8](https://doi.org/10.1186/s12937-015-0062-8).

Kiel (2015)

## The Effectiveness of a Partial Meal Replacement Program in Extremely Obese Individuals: A Systematic Retrospective Chart Review of Medifast Weight Control Centers

JR Kiel<sup>1</sup>, CD Coleman<sup>1</sup>, AH Mitola<sup>2</sup>, JS Langford<sup>1</sup>, KN Davis<sup>1</sup>, LM Arterburn<sup>1</sup><sup>1</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., 11445 Cronhill Drive, Owings Mills, MD, USA and <sup>2</sup>Independent Consultant, Clifton Park, NY, USA.

### PURPOSE/OBJECTIVE:

Extreme obesity is associated with elevated risks of morbidities and mortality, and the prevalence of this condition has been rising. Lifestyle interventions are the cornerstone of all treatment options, yet relatively few studies have assessed the effectiveness of commercial programs for attaining clinically meaningful weight loss ( $\geq 5\%$ ) in this population. The purpose of this study was to evaluate the effectiveness of the Medifast 5 & 2 & 2 Plan™ administered along with counseling in obese adults, a majority of whom were extremely obese.

### METHODS/DESIGN:

We conducted a systematic retrospective chart review of 62 obese clients from 17 Medifast Weight Control Centers\* (MWCCs). Weight, body composition and cardiometabolic risk factor data were abstracted through 24 weeks. Data were recorded electronically, and key data points were independently verified. The primary endpoint was change from baseline body weight at 12 weeks, assessed using Wilcoxon signed rank tests.

### RESULTS:

The population consisted of 57% men, and 82% had a body mass index of  $\geq 40$  kg/m<sup>2</sup>. Mean body weight among completers was reduced by  $12.9 \pm 7.1$  kg (-8.6%, n=37) at the 12-week primary endpoint and by  $19.3 \pm 11.4$  kg (-12.5%, n=17) at 24 weeks ( $p < 0.0001$ ). At 12 and 24 weeks, 76% and 88% of those remaining on the plan, respectively, had lost  $\geq 5\%$  of their baseline body weight. Fat mass accounted for a majority (68-80%) of the weight lost, resulting in improvements in body composition. Significant improvements in blood pressure and central adiposity were also observed. Program adherence was  $>80\%$ , and the meal plan was well-tolerated.

### CONCLUSIONS:

The 5 & 2 & 2 Plan used at MWCCs was effective for achieving clinically meaningful weight loss and improving cardiometabolic risk factors in a population of extremely obese individuals. This lifestyle program represents a viable first line approach for meeting treatment goals in extremely obese adults. #NCT02150837.

### REFERENCE:

Kiel J.R., Coleman C.D., Mitola A.H., Langford J.S., Davis K.N., Arterburn L.M. (2015) The Effectiveness of a Partial Meal Replacement Program in Extremely Obese Individuals: A Systematic Retrospective Chart Review of Medifast Weight Control Centers. *J Obes Weight Loss Ther*, 5S:007. doi: <http://dx.doi.org/10.4172/2165-7904.S5-007>.

## DIABETES

Coleman (2017)

### Comparative Effectiveness of a Portion-Controlled Meal Replacement Program for Weight Loss in Adults With and Without Diabetes/High Blood Sugar

CD Coleman<sup>1</sup>, JR Kiel<sup>1</sup>, AH Mitola<sup>2</sup>, LM Arterburn<sup>1</sup>

<sup>1</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., 11445 Cronhill Drive, Owings Mills, MD, USA and <sup>2</sup>Independent Consultant, Clifton Park, NY, USA.

#### PURPOSE/OBJECTIVE:

Individuals with type 2 diabetes (DM2) may be less successful at achieving therapeutic weight loss than their counterparts without diabetes. This study compares weight loss in a cohort of adults with DM2 or high blood sugar (D/HBS) to a cohort of adults without D/HBS. All were overweight/obese and following a reduced or low-calorie commercial weight-loss program incorporating meal replacements (MRs) and one-on-one behavioral support.

#### METHODS/DESIGN:

Demographic, weight, body composition, anthropometric, pulse and blood pressure data were collected as part of systematic retrospective chart review studies. Differences between cohorts by D/HBS status were analyzed using Mann-Whitney *U*-tests and mixed model regression.

#### RESULTS:

A total of 816 charts were included (125 with self-reported D/HBS). The cohort with D/HBS had more males (40.8 vs 25.6%), higher BMI (39.0 vs 36.3 kg/m<sup>2</sup>) and was older (56 vs 48 years). Among clients continuing on program, the cohorts with and without D/HBS lost, on average, 5.6 vs 5.8 kg (NS) (5.0 vs 5.6%; *p*=0.005) of baseline weight at 4 weeks, 11.0 vs 11.6 kg (NS) (9.9 vs 11.1%; *p*=0.027) at 12 weeks and 16.3 vs 17.1 kg (13.9 vs 15.7%; NS) at 24 weeks, respectively. In a mixed model regression controlling for baseline weight, gender and meal plan, and an intention-to-treat analysis, there was no significant difference in weight loss between the cohorts at any time point. Over 70% in both cohorts lost ≥5% of their baseline weight by the final visit on their originally assigned meal plan. Both cohorts had significant reductions from baseline in body fat, blood pressure, pulse and abdominal circumference.

#### CONCLUSIONS:

Adults who were overweight/obese and with D/HBS following a commercial weight-loss program incorporating MRs and one-on-one behavioral support achieved therapeutic weight loss. The program was equally effective for weight loss and reductions in cardiometabolic risk factors among adults with and without D/HBS.

#### REFERENCE:

Coleman C.D., Kiel J.R., Mitola A.H., Arterburn L.M. (2017) Comparative Effectiveness of a Portion-Controlled Meal Replacement Program for Weight Loss in Adults With and Without Diabetes/High Blood Sugar. *Nutr Diabetes*; 7(7):e284. doi: [10.1038/nutd.2017.32](https://doi.org/10.1038/nutd.2017.32).

## DIABETES

Cheskin (2008)

### Efficacy of Meal Replacements Versus a Standard Food-Based Diet for Weight Loss in Type 2 Diabetes: A Controlled Clinical Trial

LJ Cheskin, AM Mitchell, AD Jhaveri, AH Mitola, LM Davis, RA Lewis, MA Yep, TW Lycan

From the Johns Hopkins Bloomberg School of Public Health, Department of International Health, Center for Human Nutrition, Baltimore, Maryland.

#### PURPOSE/OBJECTIVE:

The purpose of this study is 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 obese participants with type 2 diabetes.

#### METHODS/DESIGN:

This study is a university-based, controlled clinical trial. Participants were 119 men and women with diabetes with a body mass index between 25 and 40 kg/m<sup>2</sup>, assigned randomly to one of two 34-week, 75% of predicted energy need diets (portion controlled or standard, self-selected, food based) and then followed by 1-year of maintenance.

#### RESULTS:

Using intention-to-treat (ITT) 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.

#### CONCLUSIONS:

A diet using portion-controlled meal replacements yielded significantly greater initial weight loss and less regain after 1 year of maintenance than a standard, self-selected, food-based diet. As PCDs may help obese patients with type 2 diabetes adhere to a weight control program, diabetes educators may consider recommending them as part of a comprehensive approach to weight control.

#### REFERENCE:

Cheskin L.J., Mitchell A.M., Jhaveri A.D., Mitola A.H., Davis L.M., Lewis R.A., Yep, M.A., Lycan T.W. (2008) Efficacy of Meal Replacements Versus a Standard Food-Based Diet for Weight Loss in Type 2 Diabetes: A Controlled Clinical Trial. *Diabetes Educ*, 34(1), 118-127. doi: [10.1177/0145721707312463](https://doi.org/10.1177/0145721707312463).

## POLYCYSTIC OVARIAN SYNDROME (PCOS)

Yuh (2011)

### Efficacy of a Hypocaloric Weight Management Program in Obese Women with Polycystic Ovarian Syndrome (PCOS)

J Yuh<sup>1</sup>, D Debrakeleer<sup>1</sup>, W McIntyre<sup>1</sup>, C Coleman<sup>2</sup>, L Fox<sup>2</sup>, L Barmat<sup>3</sup>

<sup>1</sup>Department of Obstetrics and Gynecology, Abington Memorial Hospital, 1200 Old York Road, Abington, PA, United States, 19001;

<sup>2</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., 11445 Cronhill Drive, Owings Mills, MD, United States, 21117 and ; <sup>3</sup>Department of Obstetrics and Gynecology, Grand View Hospital, 700 Lawn Avenue, Sellersville, PA, United States, 18960.

#### PURPOSE/OBJECTIVE:

To evaluate the efficacy of a hypocaloric diet program utilizing a health coach on body weight and changes in biochemical and metabolic profiles in obese PCOS patients.

#### METHODS/DESIGN:

A prospective study conducted in a teaching community hospital. Subjects were obese (BMI 33.1 ± 3.0), adult, nonpregnant women age 20-39 (27.7 ± 6.1) with PCOS defined by Rotterdam criteria. Subjects were eligible if they were free of hormonal medications for ≥3 months, were nonsmokers, and did not have diabetes or hypertension. For 3 months patients followed a 1000 calorie diet plan with the guidance of a health coach consisting of 5 Medifast meals and one self-prepared meal. Meetings with the health coach, weight measurement, and lab draws occurred on a monthly basis. The primary outcome was change in body weight; secondary outcomes were biochemical and metabolic changes. Paired t-tests were used to examine the longitudinal changes from baseline. Significance was defined as p<0.05.

#### RESULTS:

Eleven subjects completed the study. The hypocaloric diet resulted in significant decline in body weight (-18.2 ± 6.85 lbs; p<0.0001), 2-hour oral glucose (-23.0 ± 22.4 mg/dl; p=0.010), 2-hour insulin (-79.1 ± 76.6 mIU/ml; p=0.022), and calculated free androgen index (-3.7 ± 2.54; p=0.017). There was a marginally significant increase in SHGB (+9.2 ± 14.1 nmol/L; p=0.069). For subjects with elevated levels at baseline, significant improvements were found in total cholesterol (-37.0 ± 13.90 mg/dl; p=0.013), LDL cholesterol (-28.0 ± 10.80 mg/dl; p=0.014), and triglycerides (-90.0 ± 1.41 mg/dl; p=0.007). Overall, 1/3 of previously anovulatory women began ovulating and 7 out of 11 began regular menstruation.

#### CONCLUSIONS:

Significant improvements in body weight and biochemical and metabolic markers were achieved in obese PCOS subjects after 3 months following a hypocaloric portion controlled diet plan under the guidance of a health coach making conditions more favorable for ovulation.

#### REFERENCE:

*This abstract was accepted and presented as a poster at the American Society for Reproductive Medicine's 67th Annual Meeting in 2011.*

Yuh J, Debrakeleer D, McIntyre W, Coleman C, Fox L, Barmat, L. Efficacy of a Hypocaloric Weight Management Program in Obese Women with Polycystic Ovarian Syndrome (PCOS)[abstract]. 9th Annual Meeting of Androgen Excess & PCOS Society; 2011 Oct 13 - 15; Abstract nr 21.



## SENIORS

Serra (2019)

### Effects of a Hypocaloric, Nutritionally Complete, Higher Protein Meal Plan on Regional Body Fat and Cardiometabolic Biomarkers in Older Adults with Obesity

MC Serra<sup>1</sup>, DP Beavers<sup>2</sup>, RM Henderson<sup>3</sup>, JL Kelleher<sup>1</sup>, JR Kiel<sup>4</sup>, KM Beavers<sup>5</sup>

<sup>1</sup>Department of Medicine, Atlanta VA Medical Center, Emory University School of Medicine, Atlanta, GA, USA; <sup>2</sup>Department of Biostatistical Sciences, Wake Forest School of Medicine, Winston-Salem, NC, USA; <sup>3</sup>Department of Internal Medicine, Section on Gerontology and Geriatric Medicine, Winston-Salem, NC, USA; <sup>4</sup>Medifast, Inc., Baltimore, MD, USA; <sup>5</sup>Department of Health and Exercise Science, Wake Forest University, Winston-Salem, NC, USA

#### PURPOSE/OBJECTIVE:

Whether improvements in cardiometabolic health following weight loss (WL) are associated with changes in regional body fat distribution (gluteal vs. android) is not well documented.

#### METHODS/DESIGN:

Older (age: 70 ± 4 years; mean ± SD) adults with obesity were randomized to a 6-month WL program (WL; n=47), accomplished using a hypocaloric, nutritionally complete, higher protein (targeting ≥1.0 g/kg/day) meal plan, or a weight stability (WS; n=49) program. Android, gynoid, visceral, and subcutaneous abdominal fat masses (via dual energy X-ray absorptiometry) and fasting glucose and lipid profiles were assessed at baseline and 6 months.

#### RESULTS:

The WL group lost more body weight (WL: -8.6% vs. WS: -1.7%, p<0.01), resulting in a reduction in fat mass at each region only following WL (all p<0.05). The decline in the ratio of android/gynoid fat mass also was significant only following WL, resulting in greater declines than WS (mean [95% CI]; WL: -0.026 [-0.040 to -0.011] vs. WS: 0.003 [-0.012 to 0.019] g, p<0.01). The change in the ratio of visceral/subcutaneous abdominal fat mass was not significant in either group and did not differ between groups (WL: 0.65 [-0.38 to 1.68] vs. WS: 0.05 [-1.00 to 1.10] g, p=0.42). In general, the improvements in glucose and lipid profiles were associated with declines in fat mass at the gynoid and android regions (r's=0.20-0.42, all p<0.05), particularly the visceral depot but not the ratios.

#### CONCLUSIONS:

WL achieved via a hypocaloric, nutritionally complete, higher protein meal plan is effective in reducing body fat in the android, gynoid, and visceral depots, which relate to cardiometabolic improvements.

#### REFERENCE:

Serra M.C., Beavers D.P., Henderson R.M., Kelleher J.L., Kiel J.R., Beavers K.M. (2019) Effects of a Hypocaloric, Nutritionally Complete, Higher Protein Meal Plan on Regional Body Fat and Cardiometabolic Biomarkers in Older Adults with Obesity. *Ann Nutr Metab.*, 74(2):149-155. doi: [10.1159/000497066](https://doi.org/10.1159/000497066).

## SENIORS

Weaver (2019)

### Effect of a Hypocaloric, Nutritionally Complete, Higher Protein Meal Plan on Bone Density and Quality in Older Adults with Obesity: A Randomized Trial

AA Weaver<sup>1</sup>, DK Houston<sup>2</sup>, SA Shapses<sup>3</sup>, MF Lyles<sup>2</sup>, RM Henderson<sup>2</sup>, DP Beavers<sup>4</sup>, AC Baker<sup>1</sup>, KM Beavers<sup>5</sup>

<sup>1</sup>Department of Biomedical Engineering, Wake Forest School of Medicine, Winston-Salem, NC; <sup>2</sup>Department of Internal Medicine, Section on Gerontology and Geriatric Medicine; <sup>3</sup>Department of Nutritional Sciences; <sup>4</sup>Department of Biostatistical Sciences, Rutgers University, New Brunswick, NJ; <sup>5</sup>Department of Health and Exercise Science, Wake Forest University, Winston-Salem, NC

#### PURPOSE/OBJECTIVE:

Dietary protein and micronutrients are important to the maintenance of bone health and may be an effective countermeasure to weight-loss-associated bone loss.

We aimed to determine the effect of a 6-mo hypocaloric, nutritionally complete higher-protein meal plan on change in bone density and quality as compared with weight stability in older adults using a randomized post-test design. We hypothesized that participants randomly assigned to this meal plan would maintain similar bone density and quality to weight-stable controls, despite significant reductions in body mass.

#### METHODS/DESIGN:

Ninety-six older adults (70 ± 3.7 y, 74% women, 27% African American) with obesity [body mass index (kg/m<sup>2</sup>): 35.4 ± 3.3] were randomly assigned to a 6-mo hypocaloric, nutritionally complete, higher-protein meal plan targeting ≥1.0 g protein · kg body weight<sup>-1</sup> · d<sup>-1</sup> [weight loss (WL) group; n=47] or to a weight-stability (WS) group targeting 0.8 g protein · kg body weight<sup>-1</sup> · d<sup>-1</sup>, the current Recommended Dietary Allowance (n=49). The primary outcome was total hip bone mineral density (BMD), with femoral neck BMD, lumbar spine BMD, and lumbar spine trabecular bone score (TBS) as secondary outcomes, all assessed at baseline and 3 and 6 mo with dual-energy X-ray absorptiometry.

#### RESULTS:

Baseline total hip, femoral neck, and lumbar spine BMDs were 1.016 ± 0.160, 0.941 ± 0.142, and 1.287 ± 0.246 g/cm<sup>2</sup>, respectively; lumbar TBS was 1.398 ± 0.109. Despite significant weight loss achieved in the WL group (6.6 ± 0.4 kg; 8.6% ± 0.4% of baseline weight), 6-mo regional BMD estimates were similar to the WS group (all p>0.05). Lumbar spine TBS significantly increased at 6 mo in the WL group (mean: 1.421; 95% CI: 1.401, 1.441) compared with the WS group (1.390; 95% CI: 1.370, 1.409; p=0.02).

#### CONCLUSIONS:

Older adults on a hypocaloric, nutritionally complete higher-protein meal plan maintained similar bone density and quality to weight-stable controls. Our data suggest adherence to this diet does not produce loss of hip and spine bone density in older adults, and may improve bone quality. This trial was registered at clinicaltrials.gov as NCT02730988.

#### REFERENCE:

Weaver A.A., Houston D.K., Shapses S.A., Lyles M.F., Henderson R.M., Beavers D.P., Baker A.C., Beavers K.M. (2019) Effect of a Hypocaloric, Nutritionally Complete, Higher Protein Meal Plan on Bone Density and Quality in Older Adults with Obesity: A Randomized Trial. *Am J Clin Nutr.* 109(2):478-486. doi: <https://doi.org/10.1093/ajcn/nqy237>.

## SENIORS

### Beavers (2018)

#### Effect of an Energy-Restricted, Nutritionally Complete, Higher Protein Meal Plan on Body Composition and Mobility in Older Adults with Obesity: A Randomized Controlled Trial

KM Beavers<sup>1</sup>, BA Nesbit<sup>1</sup>, JR Kiel<sup>2</sup>, JL Sheedy<sup>1</sup>, LM Arterburn<sup>2</sup>, AE Collins<sup>1</sup>, SA Ford<sup>1</sup>, RM Henderson<sup>3</sup>, CD Coleman<sup>2</sup>, DP Beavers<sup>4</sup>

<sup>1</sup>Department of Health and Exercise Science, Wake Forest University, Winston-Salem, North Carolina; <sup>2</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., Baltimore, Maryland; <sup>3</sup>Department of Internal Medicine, Section on Gerontology and Geriatric Medicine, Winston-Salem, North Carolina; <sup>4</sup>Department of Biostatistical Sciences, Wake Forest School of Medicine, Winston-Salem, North Carolina.

#### PURPOSE/OBJECTIVE:

Increasing protein content of the diet might be an effective strategy to preserve muscle mass in older adults undergoing caloric restriction, thereby preserving muscle function.

#### METHODS/DESIGN:

Ninety-six older adults (70 ± 3.7 years, 74% women, 27% African American) with obesity (35.4 ± 3.3 kg/m<sup>2</sup>; 47% total body fat) were randomized to a 6-month higher protein (providing 1.2-1.5 g/kg/d) weight loss (WL) program, utilizing the Medifast 4 & 2 & 1 Plan, or to weight stability (WS). Dual-energy x-ray absorptiometry-acquired total body mass and composition, and fast gait speed over 400 m was assessed at baseline, 3, and 6 months.

#### RESULTS:

At baseline, dual-energy x-ray absorptiometry-acquired total body, fat, and lean masses were 95.9 ± 14.6, 44.6 ± 7.6, and 48.7 ± 9.5 kg, respectively, and 400-m gait speed was 1.17 ± 0.20 m/s. Total body mass was significantly reduced in the WL group (-8.17 [-9.56, -6.77] kg) compared to the WS group (-1.16 [-2.59, 0.27] kg), with 87% of total mass lost as fat (WL: -7.1 [-8.1, -6.1] kg; -15.9% change from baseline). A differential treatment effect was not observed for change in lean mass (WL: -0.81 [-1.40, -0.23] kg vs WS: -0.24 [-0.85, 0.36] kg). Four-hundred-meter gait speed was also unchanged from baseline although trends suggest slightly increased gait speed in the WL group [0.01 (-0.02, 0.04) m/s] compared with the WS group [-0.02 (-0.05, 0.01) m/s].

#### CONCLUSIONS:

Intentional weight loss using a high-protein diet is effective in producing significant total body mass and fat mass loss, while helping preserve lean body mass and mobility, in relatively high-functioning older adults with obesity.

#### REFERENCE:

Beavers K.M., Nesbit B.A., Kiel J.R., Sheedy J.L., Arterburn L.M., Collins A.E., Ford S.A., Henderson R.M., Coleman C.D., Beavers D.P. (2018) Effect of an Energy-Restricted, Nutritionally Complete, Higher Protein Meal Plan on Body Composition and Mobility in Older Adults with Obesity: A Randomized Controlled Trial. *J Gerontol A Biol Sci Med Sci: Series A.*, 74(6): 929-935 doi: [10.1093/gerona/gly146](https://doi.org/10.1093/gerona/gly146).

## SENIORS

Shaver (2018)

### Effective of Intentional Weight Loss on Mortality Biomarkers in Older Adults With Obesity

LN Shaver<sup>1</sup>, DP Beavers<sup>2</sup>, J Kiel<sup>3</sup>, SB Kritchevsky<sup>4</sup>, KM Beavers<sup>1</sup>

<sup>1</sup>Department of Health and Exercise Science, Wake Forest University, Winston-Salem, North Carolina. <sup>2</sup>Department of Biostatistical Sciences, Wake Forest School of Medicine, Winston-Salem, North Carolina. <sup>3</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., Baltimore, Maryland. <sup>4</sup>Sticht Center for Healthy Aging and Alzheimer's Prevention, Wake Forest School of Medicine, Winston-Salem, North Carolina.

#### PURPOSE/OBJECTIVE:

Observational research has identified several mortality biomarkers; however, their responsiveness to change is unknown. We tested whether the Healthy Aging Index (HAI) and other mortality biomarkers were responsive to intentional weight loss (WL), which is associated with lower mortality risk in recent meta-analyses.

#### METHODS/DESIGN:

Older adults (70.3 ± 3.7 years) with obesity were randomized into a 6-month WL (n=47) or weight stability (WS: ±5% baseline weight; n=48) program. Baseline and 6-month HAI score (0-10) was calculated from component sum (each 0-2: systolic blood pressure, forced vital capacity [FVC], creatinine, fasting blood glucose [FBG], Montreal Cognitive Assessment), and gait speed, grip strength, Digit Symbol Substitution Test, FEV<sub>1</sub>, Interleukin-6, C-Reactive Protein, and Cystatin-C were assessed at baseline and 6 months.

#### RESULTS:

Mean baseline HAI was 3.2 ± 1.6. By 6 months, WL participants lost 8.87 (95% CI: -10.40, -7.34) kg, whereas WS participants remained weight stable. WL group reduced HAI score (WL: -0.75 [95% CI: -1.11, -0.39] vs WS: -0.22 [95% CI: -0.60, 0.15]; p=0.04), and components changing the most were FBG (WL: -3.89 [95% CI: -7.78, 0.00] mg/dL vs WS: 1.45 [95% CI: -2.61, 5.50] mg/dL; p=0.047) and FVC (WL: 0.11 [95% CI: -0.01, 0.23] L vs WS: -0.05 [95% CI: -0.17, 0.08] L; p=0.06). Among other biomarkers, only Cystatin-C significantly changed (WL: -2.53 [95% CI: -4.38, -0.68] ng/mL vs WS: 0.07 [95% CI: -1.85, 1.98] ng/mL; p=0.04). Combining treatment groups, 1 kg WL was associated with a 0.07 (95% CI: 0.03, 0.12) HAI reduction (p<0.01).

#### CONCLUSIONS:

Intentional WL via caloric restriction reduced HAI score by 0.53 points, largely attributable to metabolic and pulmonary improvements.

#### REFERENCE:

Shaver L.N., Beavers D.P., Kiel J., Kritchevsky S.B., Beavers K.M. (2018). Effect of Intentional Weight Loss on Mortality Biomarkers in Older Adults with Obesity. *J Gerontol A Biol Sci Med Sci: Series A*. doi: [10.1093/gerona/gly192](https://doi.org/10.1093/gerona/gly192).

## SENIORS

Normandin (2018)

### Feasibility of Weighted Vest use During a Dietary Weight Loss Intervention and Effects on Body Composition and Physical Function in Older Adults

E Normandin<sup>1</sup>, D Yow<sup>1</sup>, C Crotts<sup>1</sup>, J Kiel<sup>2</sup>, KM Beavers<sup>3</sup>, BJ Nicklas<sup>1,3</sup>

<sup>1</sup>Section on Gerontology and Geriatric Medicine, Wake Forest School of Medicine, Winston-Salem, NC 27157, USA; <sup>2</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., Baltimore, MD 21202, USA; <sup>3</sup>Department of Health and Exercise Science, Wake Forest University, Winston-Salem, NC 27109, USA.

#### PURPOSE/OBJECTIVE:

While intentional weight loss in older adults with obesity yields clinically important health benefits there is a need to minimize the negative effects of weight loss on concomitant loss of muscle mass and strength. Data show wearing weighted vests during exercise improves lean mass and lower extremity strength, however the efficacy of wearing a weighted vest during a period of weight loss to mitigate muscle and strength loss is not known.

This study examined the feasibility of daily weighted vest use during a dietary weight loss intervention, and examined effects of vest use on body composition and physical function in well-functioning older adults with obesity.

#### METHODS/DESIGN:

*Design:* Randomized, controlled pilot study. *Setting:* Wake Forest Baptist Medical Center in Winston-Salem, NC. *Participants:* 37 older (age=65-79 years), obese (BMI=30-40 kg/m<sup>2</sup>) sedentary men and women. *Interventions:* 22-week behavioral diet intervention (targeting 10% weight loss, 1100-1300 kcals/day) with (Diet+Vest; n=20) or without (Diet; n=17) weighted vest use (goal of 10 hours/day with weight added weekly according to individual loss of body mass). *Measurements:* Body composition by dual-energy x-ray absorptiometry and measures of physical function, mobility, and muscle strength/power.

#### RESULTS:

Average weighted vest use was 6.7 ± 2.2 hours/day and the vest-wear goal of 10 hrs/day was achieved for 67 ± 22% of total intervention days. Five participants reported adverse events from wearing the vest (all back pain or soreness). Both groups lost a similar amount of weight (Diet= -11.2 ± 4.4 kg; Diet+Vest= -11.0 ± 6.3 kg; p<0.001), with no differences between groups (p=0.25). Fat mass, lean mass, and % body fat decreased significantly (p<0.0001), with no differences between groups. Compared to Diet+Vest, the Diet intervention resulted in greater decreases in leg power (p<0.02), with no other between group differences in physical function.

#### CONCLUSIONS:

This pilot study showed that vest use during dietary weight loss is feasible and safe in well-functioning older adults with obesity. Larger studies are needed to definitively determine whether external replacement of lost weight during caloric restriction may preserve lower extremity muscle strength and power.

#### REFERENCE:

Normandin E., Yow D., Crotts C., Kiel J., Beavers K.M., Nicklas B.J.(2018) Feasibility of Weighted Vest Use During A Dietary Weight Loss Intervention and Effects on Body Composition and Physical Function in Older Adults. *J of Frailty & Aging*, 7(3):198-203. doi: [10.14283/jfa.2018.17](https://doi.org/10.14283/jfa.2018.17); [PMC6489119](https://pubmed.ncbi.nlm.nih.gov/36489119/).

## SENIORS

Kelleher (2017)

### Weighted Vest Use During Dietary Weight Loss on Bone Health in Older Adults with Obesity

JL Kelleher<sup>1</sup>, DP Beavers<sup>2</sup>, RM Henderson<sup>3</sup>, D Yow<sup>3</sup>, C Crotts<sup>3</sup>, J Kiel<sup>4</sup>, BJ Nicklas<sup>1,3</sup>, KM Beavers<sup>1</sup>

<sup>1</sup>Department of Health and Exercise Science, Wake Forest University, Winston-Salem, NC 27109, USA; <sup>2</sup>Department of Biostatistics, Wake Forest University, Winston-Salem, NC 27157, USA; <sup>3</sup>Section on Gerontology and Geriatric Medicine, Wake Forest School of Medicine, Winston-Salem, NC 27157, USA; <sup>4</sup>Department of Scientific and Clinical Affairs, Medifast, Inc., Owings Mills, MD. 21117, USA.

#### PURPOSE/OBJECTIVE:

To examine the effects of daily weighted vest use during a dietary weight loss intervention, on (a) hip and spine bone mineral density (aBMD), and (b) biomarkers of bone turnover, in older adults with obesity.

#### METHODS/DESIGN:

37 older (70.1 ± 3.0 years) adults with obesity (BMI= 35.3 ± 2.9) underwent a 22 week dietary weight loss intervention (1100-1300 kcal/day) with (Diet+Vest; n=20) or without (Diet; n=17) weighted vest use (goal: 10+ h/day; weight added incrementally based on amount of weight lost). Total body weight; DXA-acquired aBMD of the total hip, femoral neck and lumbar spine; and biomarkers of bone turnover (OC, BALP, PINP, CTX) were measured at baseline and follow up. General linear models, adjusted for baseline values of the outcome and gender, were used to examine intervention effects.

#### RESULTS:

Average weight loss was significant in both groups (-11.2 ± 4.4 kg and -11.0 ± 6.3 kg, Diet+Vest and Diet groups, respectively), with no difference between groups (p=0.91). Average weighted vest use was 6.7 ± 2.2 h/day. No significant changes in aBMD or biomarkers were observed, although trends were noted for total hip aBMD and BALP. Loss in total hip aBMD was greater in the Diet group compared with Diet+Vest (Δ: -18.7 [29.3, -8.1] mg/cm<sup>2</sup> versus -6.1 [-15.7, 3.5] mg/cm<sup>2</sup>; p=0.08). BALP increased in the Diet+Vest group by 3.8% (Δ: 0.59 [-0.33, 1.50] μg/L) and decreased by -4.6% in the Diet group (Δ: -0.70 [-1.70, 0.31] μg/L, p=0.07).

#### CONCLUSIONS:

Weighted vest use during weight loss may attenuate loss of hip aBMD and increase bone formation in older adults with obesity. Further study is warranted.

#### REFERENCE:

Kelleher J.L., Beavers D.P., Henderson R.M., Yow D., Crotts C., Kiel J., Nicklas B.J., Beavers K.M. (2017). Weighted Vest Use During Dietary Weight Loss on Bone Health in Older Adults with Obesity. *J Osteopor Phys Act*, 5(4); doi: [10.4172/2329-9509.1000210](https://doi.org/10.4172/2329-9509.1000210).

## SENIORS

### Beavers (2015)

#### Effect of Protein Source During Weight Loss on Body Composition, Cardiometabolic Risk and Physical Performance in Abdominally Obese, Older Adults: A Pilot Feeding Study

KM Beavers<sup>1</sup>, MM Gordon<sup>1</sup>, L Easter<sup>2</sup>, DP Beavers<sup>3</sup>, KG Hairston<sup>4</sup>, BJ Nicklas<sup>1</sup>, MZ Vitolins<sup>5</sup>

<sup>1</sup>Department of Internal Medicine, Section on Gerontology and Geriatric Medicine; <sup>2</sup>Translational Science Institute; <sup>3</sup>Department of Biostatistical Sciences; <sup>4</sup>Department of Endocrinology and Metabolism; <sup>5</sup>Department of Epidemiology and Prevention, Wake Forest School of Medicine, Winston-Salem, NC 27157 USA.

#### PURPOSE/OBJECTIVE:

The purpose of this pilot study was to begin to examine the effect of dietary protein source (soy protein versus non-soy protein) during weight loss on body composition, and cardiometabolic and functional decline risk factors in older, abdominally obese adults.

#### METHODS/DESIGN:

*Design:* Two-arm, single-blind, randomized, controlled trial. *Setting:* Wake Forest School of Medicine, Winston-Salem NC 27157, USA. *Participants:* 25 older (68.4 ± 5.5 years, 88% female), abdominally obese (BMI: 35.1 ± 4.3 kg/m<sup>2</sup>; WC: 101.4 ± 13.1 cm) men and women were randomized to participate in the study. *Intervention:* A 12-week weight loss intervention, with participants randomized to consume soy protein-based meal replacements (S; n=12) or non-soy protein-based meal replacements (NS; n=12), in addition to prepared meals, and all participants targeted to receive an individualized calorie deficit of 500 kcal/day. *Measurements:* Body weight and composition (assessed via DXA and CT), conventional biomarkers of cardiometabolic risk, and physical performance measures were assessed pre- and post-intervention. Additional endpoints of feasibility (accrual, participation, retention, compliance, and safety) are reported.

#### RESULTS:

A total of 24 participants (87% female) completed the study (96% retention) and lost an average of 7.8 ± 3.0 kg over the 12-week period, with no difference seen between groups (p=0.83). Although nearly all measures of global and regional body composition were significantly reduced following the 12-week intervention, differences were not observed between groups. Among cardiometabolic risk factors and physical performance measures, only diastolic blood pressure was significantly lower in the NS group compared to the S group (66.7 ± 2.7 mmHg vs 73.5 ± 2.7 mmHg, respectively; p=0.04). Interestingly, in groups combined, despite significant reductions in body weight and lean mass, no significant changes in the 400-meter walk time (+5.3 ± 43.4 s), short physical performance battery score (+0.1 ± 1.0), grip strength (-0.3 ± 3.2 kg), or relative knee extensor strength (-0.0 ± 0.0 N/m/cm<sup>3</sup> thigh muscle volume) were observed.

#### CONCLUSIONS:

Data presented here suggest that a 12-week weight loss intervention, which incorporates S and NS meal replacement products, is associated with clinically significant weight loss and improvements in several parameters of cardiometabolic risk and unchanged physical function and strength. Results do not differ by protein source and suggest that soy protein is at least as good as other protein sources for weight loss during low-calorie dietary interventions in older adults.

#### REFERENCE:

Beavers K.M., Gordon M.M., Easter L., Beavers D.P., Hairston K.G., Nicklas B.J., Vitolins M.Z. (2015). Effect of Protein Source during Weight Loss on Body Composition, Cardiometabolic Risk and Physical Performance in Abdominally Obese, Older Adults: A Pilot Feeding Study. *J Nutr Health Aging*, 19(1), 87-95. doi: [10.1007/s12603-015-0438-7](https://doi.org/10.1007/s12603-015-0438-7); [PMC4818969](https://pubmed.ncbi.nlm.nih.gov/2618969/).

## TEENAGERS

Cheskin (2007)

### 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

LJ Cheskin, AH Mitola, A Mitchell, A Jhaveri, V Mitchell

International Health/Nutrition. Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland.

#### PURPOSE/OBJECTIVE:

We compared the safety and efficacy of supplemental Medifast portion-controlled meal replacements (MRs) with a USDA Food Guide Pyramid-based diet.

#### METHODS/DESIGN:

Both weight loss diets were 20% energy restricted (~500 kcal deficit). Eighty 8-15 year old children, BMI >95<sup>th</sup>ile, were screened and 40 randomized to either a MR diet (3 MRs/day during active weight loss and 2 MRs/day during maintenance) or to the food-based diet. Subjects were further randomized to dieting alone or with a parent.

#### RESULTS:

By ITT analysis, dieting with a parent, or food vs MR, made no difference in weight outcome. However, following initial weight loss (6 months) and 1 year maintenance (18 months), significant ( $p < 0.05$ ) decreases were seen in the MR group in BMI%ile (0 months=98.8 ± 1.0, 6 months=96.6 ± 3.2, 18 months=96.4 ± 3.4); body fat (5.9% at 6 months, 5.3% at 18 months); total cholesterol (6.7% [at 6 months], 5.6% [at 18 months]); LDL (19.8% [at 6 months], 7.9% [at 18 months]); and triglycerides (23.6% [at 6 months], 22.3% [at 18 months]). No significant between-group differences, differences in growth rates, or adverse events were observed.

#### CONCLUSIONS:

Among overweight 8-15 year old children, dieting with or without a parent, meal replacements were as safe and effective as a food-based diet for weight loss and maintenance.

#### REFERENCE:

*This abstract was accepted and presented as a poster at the Experimental Biology Conference in 2007.*

Cheskin L.J., Hanlon-Mitola A., Mitchell A., Jhaveri A., Yep M., Mitchell, V. (2007). 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. *FASEB J*, 21, 1b214.



## TRP64ARG GENE VARIANT

Tchernof (2000)

### Impaired Capacity to Lose Visceral Adipose Tissue During Weight Reduction in Obese Postmenopausal Women with the Trp64Arg $\beta_3$ -adrenoceptor Gene Variant

A Tchernof<sup>1</sup>, RD Starling<sup>1</sup>, A Turner<sup>1</sup>, AR Shuldiner<sup>2,3</sup>, JD Walston<sup>4</sup>, K Silver<sup>2,3</sup>, ET Poehlman<sup>1</sup>

<sup>1</sup>Department of Medicine, College of Medicine, University of Vermont, Burlington, Vermont; <sup>2</sup>Department of Medicine, the Division of Endocrinology, Diabetes and Nutrition, University of Maryland; <sup>3</sup>Geriatric Research Education and Clinical Center, Baltimore Veterans Administration Medical Center; <sup>4</sup>Division of Geriatric Medicine and Gerontology, Johns Hopkins University, Baltimore, Maryland.

#### PURPOSE/OBJECTIVE:

Controversy exists regarding the association between the Trp64Arg variant of the  $\beta_3$ -adrenoceptor gene and visceral obesity. The cross-sectional nature of most studies, the modest effect of the variant, and the sex or ethnic differences between groups have contributed to discrepancies among investigations. To overcome these confounding factors, we examined the effect of the Trp64Arg variant on total and visceral adipose tissue loss, insulin sensitivity, and cardiovascular disease risk factors in response to weight reduction in obese older women.

#### METHODS/DESIGN:

A total of 24 women (age  $57 \pm 4$  years), including 1 Trp64Arg homozygote, 10 Trp64Arg heterozygotes, and 13 normal homozygotes, were admitted to a weight reduction program of 13  $\pm$  3 months, with weight and nutritional intake stabilization established before testing. Total and regional adiposity were measured with dual-energy X-ray absorptiometry and computed tomography, insulin sensitivity was measured by the hyperinsulinemic-euglycemic clamp technique, and a blood lipid profile was obtained.

#### RESULTS:

No baseline differences were noted in adiposity measurements, glucose disposal, and lipid profiles among carriers and noncarriers of the variant allele. In response to weight loss, carriers and noncarriers of the Trp64Arg allele had similar reductions in body weight ( $-16.4 \pm 5.0$  vs.  $-14.1 \pm 6.2$  kg, NS) and body fat ( $-10.0 \pm 5.2$  vs.  $-11.5 \pm 3.9$  kg, NS). However, loss of visceral adipose tissue was 43% lower in carriers of the Trp64Arg allele compared with noncarriers ( $-46 \pm 27$  vs.  $-81 \pm 51$  cm<sup>2</sup>,  $p=0.05$ ). Furthermore, there was less improvement in the total cholesterol-to-HDL cholesterol ratio ( $-0.18 \pm 0.54$  vs.  $-0.72 \pm 0.56$ ,  $p=0.04$ ) in carriers compared with noncarriers of the allele. Although glucose disposal improved in both groups, there was no difference in the magnitude of improvement between carriers and noncarriers of the variant allele.

#### CONCLUSIONS:

In conclusion, older obese women carrying the Trp64Arg  $\beta_3$ -adrenoceptor gene variant have an impaired capacity to lose visceral adipose tissue in response to prolonged calorie restriction. Despite these genetic differences in loss of intra-abdominal adipose tissue, improvement in glucose disposal was similar between groups.

#### REFERENCE:

Tchernof A., Starling R.D., Turner A., Shuldiner A.R., Walston J.D., Silver K., Poehlman E.T. (2000). Impaired Capacity to Lose Visceral Adipose Tissue During Weight Reduction in Obese Postmenopausal Women with the Trp64Arg  $\beta_3$ -adrenoceptor Gene Variant. *Diabetes*, 49(10), 1709-1713.

## OBESITY PHARMACOTHERAPY

Moldovan (2016)

### Effects of a Meal Replacement System Alone or in Combination with Phentermine on Weight Loss and Food Cravings

CP Moldovan<sup>1\*</sup>, AJ Weldon<sup>2\*</sup>, NS Daher<sup>3</sup>, LE Schneider<sup>4</sup>, DL Bellinger<sup>5</sup>, LS Berk<sup>3,6</sup>, AC Hermé<sup>1</sup>, AL Archéiga<sup>1</sup>, WL Davis<sup>2</sup>, WR Peters<sup>7</sup>

<sup>1</sup>Department of Psychology, School of Behavioral Health; <sup>2</sup>Department of Pharmaceutical and Administrative Sciences, School of Pharmacy; <sup>3</sup>Department of Allied Health Studies, School of Allied Health Professions; <sup>4</sup>Department of Nutrition and Dietetics, School of Allied Health Professions; <sup>5</sup>Department of Pathology and Human Anatomy; <sup>6</sup>Department of Physical Therapy, School of Allied Health Professions; <sup>7</sup>Department of Preventative Medicine, School of Medicine, Loma Linda University, Loma Linda, CA, USA \*CPM and AJW contributed equally to this article.

#### PURPOSE/OBJECTIVE:

To examine the effects of phentermine combined with a meal replacement program on weight loss and food cravings and to investigate the relationship between food cravings and weight loss.

#### METHODS/DESIGN:

In a 12-week randomized, double-blind, placebo-controlled clinical trial, 77 adults with obesity received either phentermine or placebo. All participants were provided Medifast® meal replacements, were instructed to follow the Take Shape for Life® Optimal Weight 5 & 1 Plan for weight loss, and received lifestyle coaching in the *Habits of Health* program. The Food Craving Inventory and the General Food Cravings State and Trait Questionnaires were used to measure food cravings.

#### RESULTS:

The phentermine group lost 12.1% of baseline body weight compared with 8.8% in the placebo group. Cravings for all food groups decreased in both groups; however, there was a greater reduction in cravings for fats and sweets in the phentermine group compared with the placebo group. Percent weight loss correlated significantly with reduced total food cravings ( $r=0.332$ ,  $p=0.009$ ), cravings for sweets ( $r=0.412$ ,  $p<0.000$ ), and state food cravings ( $r=0.320$ ,  $p=0.007$ ).

#### CONCLUSIONS:

Both phentermine combined with a meal replacement program and meal replacements alone significantly reduced body weight and food cravings; however, the addition of phentermine enhanced these effects.

#### REFERENCE:

Moldovan C.P., Weldon A.J., Daher N.S., Schneider L.E., Bellinger D.L., Berk L.S., Hermé A.C., Archéiga A.L., Davis W.L., Peters W.R. (2016) Effects of a Meal Replacement System Alone or in Combination with Phentermine on Weight Loss and Food Cravings. *Obesity*, 24:2344-2350  
doi: [10.1002/oby.21649](https://doi.org/10.1002/oby.21649).

## OBESITY PHARMACOTHERAPY

Haddock (2008)

### Effectiveness of Medifast Supplements Combined with Obesity Pharmacotherapy: A Clinical Program Evaluation

CK Haddock<sup>1</sup>, WSC Poston<sup>1</sup>, JP Foreyt<sup>2</sup>, JJ DiBartolomeo<sup>3</sup>, PO Warner<sup>4</sup>

<sup>1</sup>University of Missouri, Kansas City School of Medicine; <sup>2</sup>Baylor College of Medicine; <sup>3</sup>Medifast, Inc.; <sup>4</sup>New Dimensions Medical Group.

#### PURPOSE/OBJECTIVE:

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.

#### METHODS/DESIGN:

We conducted a systematic program evaluation of weight loss data from a medically-supervised weight control program combining the use of MMRS and ASM. Data were obtained and analyzed from 1,351 patient (BMI  $\geq$  25) medical charts who had participated for at least 12 weeks of treatment. Outcomes included weight loss (kg) and percent weight loss from baseline at 12, 24, and 52 weeks. Both completers and intention-to-treat (ITT) analyses were conducted. Completers' (i.e., those with complete data for 52 weeks) outcomes were evaluated after stratification for reported adherence to the MMRS and ASM.

#### RESULTS:

Participants who completed 52 weeks of treatment experienced substantial weight losses at 12 (-9.4  $\pm$  5.7 kg), 24 (-12.0  $\pm$  8.1 kg), and 52 weeks (-12.4  $\pm$  9.2 kg) 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.

#### CONCLUSIONS:

This weight loss program using a combination of MMRS and ASM produced significant and sustained weight losses at 52 weeks. 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. Program retention at one year was similar to that reported in many controlled drug trials and better than most commercial programs reported in the literature.

#### REFERENCE:

Haddock C.K., Poston W.S.C., Foreyt J.P., DiBartolomeo J.J., Warner P.O. (2008). Effectiveness of Medifast Supplements Combined with Obesity Pharmacotherapy: A Clinical Program Evaluation. *Eat Weight Disord*, 13(2), 95-101.

## NON-PHARMACEUTICAL APPETITE SUPPRESSANTS

### Matalon (2000)

#### An Evaluation of Weight Loss Following a Carbohydrate and Fat Restricted Diet with Appetite Suppressant and Dietary Supplementation

V Matalon<sup>1</sup>

<sup>1</sup>TLC Healthcare, Inc., Marlton, N.J. USA.

##### PURPOSE/OBJECTIVE:

This was an open label trial designed 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.

##### METHODS/DESIGN:

Forty-seven adult patients were prescribed a carbohydrate and fat restricted diet supplemented with a natural appetite suppressant, a dietary supplement and a liquid protein drink [Medifast]. In addition, patients at risk for gallbladder disease were given ursodiol (Actigall<sup>®</sup>) 300 mg BID. At baseline, evaluations included a history and physical, and measurements of total body weight (lbs), body fat (%), BMI, lean body mass, water weight and blood pressure. Patients were then seen weekly for 6 months. At each weekly visit, total weight, % body fat, BMI, lean body mass, water weight and BP were noted.

##### RESULTS:

At the end of the study, statistically significant differences from baseline to final value were noted 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 both systolic ( $p = 0.003$ ) and diastolic ( $p < 0.001$ ) blood pressure.

##### CONCLUSIONS:

This 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 currently prescribed pharmacological agents [at the time of the study]. Patients in this 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.

##### REFERENCE:

Matalon, V. (2000). An Evaluation of Weight Loss Following a Carbohydrate and Fat Restricted Diet with Appetite Suppressant and Dietary Supplementation. *The Bariatrician*, 10-13.

## MEDIFAST PRODUCTS

Davis (2008)

### The Effect of Metabolism-Boosting Beverages on 24-hr Energy Expenditure

LM Davis<sup>1</sup>, CD Coleman<sup>1</sup>, WS Andersen<sup>1</sup>, LJ Cheskin<sup>2</sup>

Medifast, Inc., Research & Development, 11445 Cronhill Drive, Owings Mills, 21117, MD, USA; <sup>2</sup>Johns Hopkins Bloomberg School of Public Health, Department of International Health, Division of Human Nutrition, Baltimore, MD, 21205-2179, USA.

#### PURPOSE/OBJECTIVE:

The effect of thermogenic meal replacement beverages (TMRB) containing 90 mg [epigallocatechin gallate] EGCG and 100 mg of caffeine on resting energy expenditure (REE) was tested.

#### METHODS/DESIGN:

Thirty adults (19 women, 11 men) were stratified into 3 groups: lean (n=10, BMI 21.5 ± 2.1 [kg/m<sup>2</sup>]); 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 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 the TMRB (p=0.0002).

#### CONCLUSIONS:

TMRB appear to be a promising weight control tool.

#### REFERENCE:

Davis L.M., Coleman C.D., Andersen W.S., Cheskin L.J. (2008) The Effect of Metabolism-Boosting Beverages on 24-hr Energy Expenditure. *The Open Nutrition Journal*, 2(37-41).

1. Warren M, Beck S, Rayburn J. *The State of Obesity: Better Policies for a Healthier America 2018*. Washington D.C.: Robert Wood Johnson Foundation and Trust for America's Health;2018.
2. Fryar CD, Carroll MD, Ogden CL. Prevalence of overweight, obesity, and extreme obesity among adults: United States, 1960-1962 through 2011-2012. 2014.
3. Ogden CL, Carroll MD, Fryar CD, Flegal KM. Prevalence of Obesity Among Adults and Youth: United States, 2011-2014. *NCHS Data Brief*. 2015(219):1-8.
4. Hales CM, Carroll MD, Fryar CD, Ogden CL. *Prevalence of Obesity Among Adults and Youth: United States, 2015-2016*. National Center for Health Statistics;2017.
5. Fryar C, Carroll M, Ogden C. Prevalence of overweight, obesity, and extreme obesity among adults aged 20 and over: United States, 1960-1962 through 2013-2014. *National Center for Health Statistics*. 2016(July).
6. Jensen MD, Ryan DH, Apovian CM, 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. *Circulation*. 2013;128:1-69.
7. National Heart Lung and Blood Institute. What are the health risks of overweight and obesity? 2012; <http://www.nhlbi.nih.gov/health/health-topics/topics/obe/risks>. Accessed May 28th, 2015.
8. Segal LM, Rayburn J, Martin A. *The State of Obesity: Better Policies for a Healthier America 2016*. Robert Wood Johnson Foundation;2016.
9. CDC. Centers for Disease Control and Prevention (U.S.): Adult Obesity Facts. 2016; <https://www.cdc.gov/obesity/data/adult.html>. Accessed 01/10/2017, 2017.
10. WHO | Obesity and overweight. *WHO* 2018; <http://www.who.int/mediacentre/factsheets/fs311/en/>. Accessed April 4, 2018.
11. National Heart Lung and Blood Institute, National Institute of Diabetes and Digestive and Kidney Diseases (U.S.). *Clinical guidelines on the identification, evaluation, and treatment of overweight and obesity in adults : the evidence report*. Bethesda, MD: National Institutes of Health, National Heart, Lung, and Blood Institute; 1998.
12. Wing RR, Lang W, Wadden TA, et al. Benefits of modest weight loss in improving cardiovascular risk factors in overweight and obese individuals with type 2 diabetes. *Diabetes Care*. 2011;34(7):1481-1486.

13. Lau DC, Teoh H. Benefits of modest weight loss on the management of type 2 diabetes mellitus. *Can J Diabetes*. 2013;37(2):128-134.
14. Anandam A, Akinnusi M, Kufel T, Porhomayon J, El-Solh AA. Effects of dietary weight loss on obstructive sleep apnea: a meta-analysis. *Sleep Breath*. 2013;17(1):227-234.
15. Knowler WC, Barrett-Connor E, Fowler SE, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. *N Engl J Med*. 2002;346(6):393-403.
16. Anderson JW, Konz EC. Obesity and disease management: effects of weight loss on comorbid conditions. *Obes Res*. 2001;9 Suppl 4:326S-334S.
17. Heymsfield SB, van Mierlo CA, van der Knaap HC, Heo M, Frier HI. Weight management using a meal replacement strategy: meta and pooling analysis from six studies. *Int J Obes Relat Metab Disord*. 2003;27(5):537-549.
18. American Dietetic Association. Position of the American Dietetic Association: weight management. *Journal of the American Dietetic Association*. 2009;109(2):330-346.
19. Lee CL, Chee WSS. Translation of evidence to clinical practice for use of meal replacements in weight loss and obesity-lessons learned from research studies. *J Nutr Food Sci*. 2016;6:541.
20. Heymsfield SB. Meal replacements and energy balance. *Physiol Behav*. 2010;100(1):90-94.
21. Astbury NM, Piernas C, Hartmann-Boyce J, Lapworth S, Aveyard P, Jebb SA. A systematic review and meta-analysis of the effectiveness of meal replacements for weight loss. *Obes Rev*. 2019;20(4):569-587.
22. Raynor HA, Champagne CM. Position of the Academy of Nutrition and Dietetics: interventions for the treatment of overweight and obesity in adults. *Journal of the Academy of Nutrition and Dietetics*. 2016;116(1):129-147.
23. Guo X, Xu Y, He H, et al. Effects of a meal replacement on body composition and metabolic parameters among subjects with overweight or besity. *J Obes*. 2018;2018:2837367.
24. Gulati S, Misra A, Tiwari R, Sharma M, Pandey RM, Yadav CP. Effect of high-protein meal replacement on weight and cardiometabolic profile in overweight/obese Asian Indians in North India. *Br J Nutr*. 2017;117(11):1531-1540









MED  
LISTED  
NYSE

©2019 Medifast Clinical Studies Overview  
Medifast, Inc., Baltimore, Maryland

CO-0915DOC\_ClinicalStudies0919

