Current Publications on Formula 1

Introduction

This summary of published clinical studies on the use of Herbalife Formula 1 for weight management is provided as an educational service by the Herbalife Nutrition Institute. These studies were conducted using Herbalife Formula 1 in university-affliliated research centers in countries around the world: including the United States of America, Korea, Germany, Russia, China, Taiwan, Mexico, and India.

Reducing the risk of age-related chronic diseases such as diabetes and heart disease through weight management and a healthy active lifestyle are key missions of the Herbalife Nutrition Institute's. It is hoped that this summary of completed and published clinical studies will help the public and scientific community to appreciate the extensive evidence of the effects of Formula 1 on Weight Management shown through these clinical studies.

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A Controlled Trial of Protein Enrichment of Meal Replacements forWeight Reduction with Retention of Lean Body Mass

Leo Treyzon, Steve Chen, Kurt Hong, Eric Yan, Catherine L Carpenter,Gail Thames, Susan Bowerman, He-Jing Wang, Robert Elashoff and Zhaopying Li

Nutrition Journal 2008, 7:23 doi:10.1186/1475-2891-7-23

High protein diets have been shown to improve satiety and retention of lean body mass. This study was designed to determine effects of Formula 1 used as a protein-enriched meal replacement with added protein (Personalized Protein Powder) on weight loss and lean body mass retention by comparison to a control carbohydrate-enriched meal replacement placebo with the same number of calories. In addition, customized diet plans were developed to achieve high protein (30% of total calories) or standard protein intakes (15% of total calories) including foods and the meal replacements. Eighty-five subjects completed the study conducted at the University of California, Los Angeles. As expected, since the calories in both groups were the same, there were no differences in weight loss at 12 weeks (-4.19 ± 0.5 kg for the high protein group and -3.72 ± 0.7 kg for standard protein group, $p > 0.1$). However, the subjects in the high protein group (HP) lost significantly more fat weight than the standard protein (SP) group (HP = -1.65 ± 0.63 kg; SP = -0.64 ± 0.79 kg, $P = 0.05$) as estimated by bioelectrical impedance analysis.

Impact: Subjects lost more fat weight on the higher protein intake using Formula 1 as a meal replacement. See figure to the left.

Protein-Enriched Meal Replacements Do Not Adversely Affect Liver, Kidney or Bone Density: An Outpatient Randomized Controlled Trial

Zhaoping Li, Leo Treyzon, Steve Chen, Eric Yan, Gail Thames, Catherine L Carpenter

Nutrition Journal 2010, 9:72

In order to address the concern that recommending protein-enriched meal replacements as part of a weight management program could lead to changes in biomarkers of liver or renal function and reductions in bone density, this study was designed as a placebo-controlled clinical trial utilizing two meal plans providing the same number of calories utilizing either a high protein-enriched (HP) or a standard protein (SP) meal replacement in an outpatient weight loss program at the University of California, Los Angeles. 100 obese men and women over 30 years of age with a body mass index (BMI) between 27 and 40 kg/m2 were randomized to one of two weight loss meal plans with the same number of calories 1). HP group: providing 2.2 g protein/kg of lean body mass (LBM)/day or 2). SP group: providing 1.1 g protein/kg LBM/day. Meal replacement (MR) was used twice daily (one meal, one snack) for 3 months and then once a day for 9 months. Body weight, lipid profiles, liver function, renal function and bone density were measured at baseline and 12 months.

Seventy subjects completed the study. Both groups lost weight (HP -4.29 ± 5.90 kg vs. SP -4.66 ± 6.91 kg, p

Impact: Both the HP and SP diets were well tolerated, resulted in expected weight loss, were sustainable, and did not result in any adverse effects. There were no changes of liver function, renal function or bone mineral density over one year in either group using Formula 1.

Efficacy of Low-Calorie, Partial Meal Replacement Diet Plans on Weight and Abdominal Fat In Obese Subjects With Metabolic Syndrome: A Double-Blind, Randomized Controlled Trial of Two Diet Plans – One High in Protein and One Nutritionally Balanced

Lee, J. Lee, W. K. Bae, J. K. Choi, H. J. Kim, B. Cho

Int J Clin Pract, February 2009, 63, 2, 195–201

This study conducted in South Korea at the National Seoul University was designed to evaluate the efficacy of two low-calorie diets with partial meal replacement plans–a high-protein plan (HP) and a conventional protein (SP) plan–on reducing obesity in obese subjects with metabolic syndrome. In a 12-week, double-blind study, 75 participants were randomly assigned to either the high protein (HP) or conventional protein (SP) plan. The overall mean weight losses were similar at 5 kg in the HP-plan group and 4.9 kg in the SP-plan group as expected since the number of recommended calories were the same. Truncal fat mass decreased 1.6 kg in the HP-plan group and 1.5 kg in the SP-plan group as measured by Dual Energy X-Ray Absorptiometry. Whole body fat mass decreased 2.5 kg in the HP-plan group and 2.3 kg in the SP-plan group. Between-group losses did not differ significantly for truncal or whole body fat

mass in the analysis of all subjects. However, when the subjects who followed the diet plans with 70% or greater fidelity were analyzed, truncal and whole body fat mass decreased more in the HP-plan group than in the SP-plan group (-3.5 kg vs -.2.2 kg) as did abdominal fat (-1.9 kg vs -1.5 kg respectively). These differences in total and abdominal fat between groups were statistically significant (p

Impact: Both low-calorie partial meal replacement diets plans – the high-protein and the conventional – were safe and had a similar effect on weight, but the high protein diet was more effective in reducing body fat and abdominal fat in obese subjects with Metabolic Syndrome among subjects with greater than 70 percent compliance with the plan.

Enhanced Weight Loss with Protein-Enriched Meal Replacements in Subjects with the Metabolic Syndrome

Flechtner-Mors M, Boehm BO, Wittmann R, Thoma U, Ditschuneit HH.

Diabetes Metab Res Rev. 2010; 26:393-405.

This study was conducted at the University of Ulm in Germany to compare the effects of two partial meal replacement diet plans using either high or standard protein prescription in obese subjects with the Metabolic Syndrome, a common group of risk factors for chronic disease based on the levels of blood fats, sugar, blood pressure, and waist circumference. Obese subjects with Metabolic Syndrome received instructions for an energy-restricted diet with a calorie deficit of 500 kcal/day and were randomly assigned to either high-protein (1.34 g/kg body weight) or conventional protein (0.8 g/kg body weight) diets for 12 months. Protein-enriched meal replacements were used to enrich one arm of the diet with protein throughout the study. In all, 67% of the participants completed the 1-year study.

Subjects following the high-protein diet lost more body weight and more fat mass compared with those on the conventional protein diet, whereas the loss of lean mass was similar in both diet groups indicating that the higher protein helped to maintain lean mass better than the standard protein diet. Blood test measures associated with the metabolic syndrome improved in both diet groups. Improvements were greater in subjects in the high protein group. After 12 months of treatment, 64.5% of the subjects in the high-protein diet group and 34.8% of the subjects in the conventional diet group no longer met three or more of the criteria for having the metabolic syndrome.

Impact: Individuals with the metabolic syndrome achieved significant weight loss while preserving fat-free mass when treated with an energy-restricted, high-protein diet that included nutrient-dense meal replacements (Formula 1 and Personalized Protein Powder), as compared with the results for conventional protein intake. An intervention with a protein-enriched diet demonstrated advantages for the management of the metabolic syndrome which is common in middle-aged individuals globally and increases the risk for diabetes and heart disease.

The Effect of Low?Calorie Diets with Inclusion of Protein Food Substitutes on the

Anthropometric and Clinico?Biochemical Indices In Obese Patients

K.M. Gapparova, V.I. Pilipenko, Yu.G. Chekhonina, O.N. Grigoryan

Dietology Issues, 2011, v. 1, ?1, p.33?39

This study was conducted in the Scientific Research Institute of Nutrition at the Russian Academy of Medical Sciences in Moscow in order to assess the tolerance and effectiveness of low?calorie protein?modified diets a randomized controlled study was carried out on three groups of patients with obesity and overweight (30 patients in each group) aged from 21 to 60 years. The study was conducted in two phases, each lasted 3 months. The patients were divided into three groups, each consisting of 30 persons. During the 6?month observation period, two groups of patients received variants of a low?calorie diet with various protein contents by including Formula 1 and Protein Powder in their diet to substitute for two meals in the first three month period and one meal in the second three month period. The patients in the third group (control group) received a standard low?calorie diet with no meal replacements.

In the process of diet therapy, the dynamics of the indices of body composition, lipidograms, carbohydrate metabolism and also changes of the feeling of hunger and satiation were assessed. In the groups of patients receiving protein food substitutes in the diet, a significant reduction of body mass, predominantly at the expense of fatty component, was noted. In the reference group, decrease of fatty mass was accompanied by reduction of lean body mass. In two studied groups of patients with inclusion of protein food substitutes into the diet, on the background of the optimal dynamics of the feeling of hunger and satiation a tendency to normalization of the indices of lipidograms and carbohydrate metabolism was noted as compared with the group that received the standard low?calorie diet.

Impact: The results of the study support the use of Formula 1 high?protein food substitute in long?term programs of body mass reduction with the aim to enhance the effectiveness of low?calorie diets and to improve the quality of life in patients with overweight and obesity.

A Calorie-Restriction Diet Supplemented with Fish Oil and High-Protein Powder is Associated with Reduced Severity of Metabolic Syndrome In Obese Women

H-Y Su, H-C Lee, W-Y Cheng and S-Y Huang

European Journal of Clinical Nutrition (2014), 1–7

This study was carried out at the Taipei Medical University in Taiwan in order to determine the effects of a calorie-restricted diet (CR) supplemented with Formula 1 and n-3 polyunsaturated fatty acids (PUFAs) on women with Metabolic Syndrome. A total of 143 eligible female participants were recruited and assigned to four dietary interventions: 1) 1500-kcal standard calorie-reduced diet (CR); 2) a calorie-reduced diet using Formula 1 meal-replacements (CRMR);3) a calorie-restricted food diet with fish oil supplementation (CRF); 4) and a calorie-restricted diet using meal-replacements supplemented with two grams per day of fish oil capsules(CRMRF).

Among 143 female MetS patients enrolled, 136 patients completed the 12-week study. After the 12-week dietary interventions, we observed reductions in body weight and waist circumference in all groups. Triglyceride levels decreased significantly in the CRMR, CRF and CRMRF groups, but not in the CR group. In this study, patients in the two fish oil-supplemented groups consumed 10 capsules of fish oil per day or 2 grams of fish oils per day resulting in a 17% reduction in triglyceride levels in the blood. Following the interventions, the changes in waist circumference , blood pressure, fasting blood sugar, and triglycerides significantly correlated with the reductions in the severity of Metabolic Syndrome. The Metabolic Syndrome is also associated with a pro-inflammatory tendency measured as elevated levels of C-reactive protein. Calorie restriction with low fat diet alone or fish oils alone did not decrease C-reactive protein, but using Formula 1 and fish oils together resulted in reduced levels of C-reactive protein.

Impact: This study demonstrated that Formula 1 combined with Fish Oils can reduce the severity of metabolic syndrome in women by approximately twofold in comparison With A Standard Diet.

Effects of Calorie Restriction with N-3 Long-Chain Polyunsaturated Fatty Acids on Metabolic Syndrome Severity in Obese Subjects: A Randomized-Controlled Trial

Lee H-C, Cheng W-Y, Hsu Y-H, Su H-Y,Brian E. T.-G. Huang B.E.T-G, Lin Y-K ,Wing P. Chan F,Su C-T, Huang S-Y

Journal of Functional Foods 2015

In this study conducted in Taipei Medical University in Taiwan, Obese individuals with Metabolic Syndrome were randomly assigned to receive a partial meal replacement diet utilizing Formula 1 alone or Formula 1 in combination with fish oil supplementation. Comparison groups received a calorically restricted food diet alone or a calorie-restricted diet and fish oil supplementation. The 188 participants were randomly assigned one of four calorie-restriction diets for 12 weeks: calorie-restriction (n = 44), calorie restriction meal replacement (n = 45), calorie-restriction with fish oil (n = 44), or calorie restriction meal replacement with fish oil (n = 44); 179 participants completed the trial. In addition to previously reported improvements in biomarkers of the Metabolic Syndrome in a smaller number of patients, this publication reported improved circulating fatty acid profiles noted as increasing the levels of eicosapentanoic acid (EPA) in all the groups except the simple caloric restricition without use of Formula 1. Since Formula 1 replaces meals with omega-6 fats as hidden oils, Formula 1 alone improves the omega-3 to omega-6 ratio by reducing omega-6. However, adding fish oils to the plan using Formula 1 further improves the omega-6 to omega-3 ratio by increasing omega-3. When fish oil is added to the calorie-restricted diet, it also increases the omega-3 measured as EPA. However, the calorie-restricted diet by simply reducing total calorie intake does not change the relative amounts of omega-3 and omega-6 fatty acids in the blood.

Impact: The interaction between F1 in a meal replacement diet and fish oil supplementation was demonstrated in this study. Formula 1 meal replacement significantly improved serum omega-3 fatty acid levels relative to omega-6 fatty acids by reducing hidden fats in the diet which are pro-inflammatory. The effect of Formula 1 on omega-3 fatty acid to omega-6 fatty acid ratios was increased by adding fish oil supplementation to the Formula 1 diet plan.

The Effect of Protein-enriched Meal Replacement on Waist Circumference Reduction among Overweight and Obese Chinese with Hyperlipidemia

Chen W, Liu Y, Yang Q, Li X, Yang J, Wang J, Shi L, Chen Y, Zhu S

***J American College of Nutrition* (2015)**

This study was conducted at the Nutrition Department of the Union Medical College Hospital, the Department of Endocrinology at the 306 Hospital of Peoples Liberation Army, the Nutrition of the Sino-Japan Friendship Hospital, and the Statistics Department of the First Hospital of Peking University in China in order to examine for the first time the effects of Formula 1 protein-rich meal replacement in a population that typically eats a very low protein breakfast. In 2002, it was estimated that nearly 40% of middle-aged and elderly people in urban China were overweight, and nearly 20% were obese.

One hundred and eight male and female patients who met all inclusion criteria and none of the exclusion criteria were randomized 1:1 to a high-protein (HP) diet (2.2 g protein/kg/day) or a standard-protein (SP) diet (1.1 g protein/kg/day) using Formula 1. Meal replacements were consumed twice daily for 3 months. Assessments included body weight, waist-hip ratio, body fat percentage, blood lipids, blood glucose, insulin, liver and kidney function. At week 12, the weight loss was -3.38 ±2.65 kg for the HP group and -2.72 ±2.84 kg for the SP group Although mean weight loss and percent BMI reduction were greater with HP than SP at 12 weeks, the differences were not significant. There was, however, a significantly greater decrease in waist-hip ratio with HP versus SP.

Impact: This is the first study on meal replacements in overweight and obese Chinese. Both HP and SP groups were prescribed the same number of calories so the similar weight losses were expected. While percent body fat was not different between groups, there was a change from baseline in percent body fat in the HP group but not in the SP group. Moreover, there was a decrease in waist circumference only in the HP group suggesting a decrease in abdominal fat.

Effect of A High Protein Diet Versus Standard Protein Diet on Weight Loss and Biomarkers of Metabolic Syndrome: A Randomized Clinical Trial

Ismael Campos-Nonato I, Hernández L, and Barquera S.

Obesity Facts 2017; 10:238-251

This study was conducted at the Center for Research in Nutrition and Health. Mexican National Institute of Public Health in Cuernavaca Mexico in order to determine the effect of increased protein intake using Formula 1 as part of a meal replacement program on weight loss in Mexican adults with Metabolic Syndrome. The prevalence of metabolic syndrome is approximately 25% of the worldwide adult population and 49.8% in Mexicans. 118 adults meeting criteria for Metabolic Syndrome were randomized to prescribed hypocaloric diets (500kcal less than resting metabolism providing either 0.8 g/kg body weight proteimn (SP

group) or 1.34 g/kg body weight (HP group) protein for 6 months. 105 subjects (51 for SP and 54 for HP) completed the trial. Overall weight loss was 5.1±3.6 kg in the SP group compared to 7.0±3.7 kg in the in the HP group. Decreased waist circumference was noted in both groups (HP= -8.8±2.6 percent and SP= -6.5±2.6 percent). In the subgroup judged to be adherent more than 75% of the time with the prescribed diets, there was a significant difference in mean weight loss between the HP and SP groups (HPD -9.5% vs. SPD -5.8%) In a study in free-living subjects reduced compliance may have obscured the effects of the higher protein plan on satiety and weight loss.

Impact: This was the first study conducted in Mexico that investigated the impact of partial diet replacement with protein-enriched meal in individuals with metabolic syndrome, although there have been similar studies in overweight and obese adults conducted in other countries. Formula 1 meal replacements improved adherence to the diet by offering a simple and healthy alternative meal option that resulted in improvements in biomarkers of Metabolic Syndrome in both the high and standard protein groups.

Effect of High Protein Meal Replacement on Weight And Cardiometabolic Profile in Overweight/Obese Asian Indians in North India

Gulati S, Misra A, Tiwari R, Sharma M, Pandey RM, Yadav CP

British Journal of Nutrition 2017

This study was conducted at the Fortis C-DOC Center for Excellence for Diabetes, Metabolic Disease and Endocrinology, and the All India Institute of Medical Sciences in New Delhi, India evaluate the impact of high protein meal replacement (HPMR) on weight, and metabolic, lipids and inflammatory parameters in overweight/obese Asian Indians. Diets consumed by Asian Indians are high in refined carbohydrates, saturated and trans-fats, salt, sugar and low in fiber, omega 3 polyunsaturated fatty acids and protein. There is a lower intake of protein in Asian Indians (10.8% in rural and 10.9% in urban population) vs. north Americans in USA (nearly 16%). A total of 122 overweight/obese men and women were prescribed a high protein meal replacement plan or control diet after a 2 weeks stabilization. One hundred subjects completed the study and demonstrated a fat mass loss of 3.4 Kg with high protein Formula 1 based diet as compared to 0.7 Kg in the control diet. A 2.8 cm reduction in waist circumference with the high protein meal replacement diet as compared to the control diet.

Impact: This study demonstrated for the first time in Asian Indians that a high protein meal replacement diet using Formula 1 resulted in significant weight loss, reduction in waist circumferenc, body fat mass, and numerous biomarkers of Metabolic Syndrome. These findings are of practical and clinical significance keeping in mind the body composition and nutritional state of Asian Indians, and their high risk of Metabolic Syndrome.

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