
Effect of a Dietary Supplement Combination on Weight Management, Adipose Tissue, Cholesterol and Triglycerides in Obese Subjects

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A combination dietary supplement containing vitamins, minerals, herbs, fibers and amino acids was studied to determine its safety and efficacy on weight/fat loss, cholesterol and triglycerides in a double-blind, placebo-controlled trial. Total body weight, body fat %, waist and hip measurements, total cholesterol and triglycerides were evaluated before and after 6 weeks treatment with combination supplement or placebo. The study population consisted in 27 mildly to moderately obese, otherwise healthy, volunteers. After 6 weeks of treatment, the combination supplement had a statistically significant ($p < 0.001$, $\mu = 0.05$) positive weight reducing effect (-8.59Lb vs. +2.14 Lb). This

weight reduction was associated with a corresponding statistically significant ($p < 0.001$, $\mu = 0.05$) decrease in body fat % in the treatment group (-2.88%) vs. the placebo (+0.86%). In addition, significant decreases in total cholesterol (-22.94 mg/dL) and triglycerides (-39.29 mg/dL) were obtained plus reductions in waist and hip measurements. These positive results lead us to conclude, that the combination supplement studied herein is a safe and effective way to assist in weight/fat reduction and decreases in total cholesterol and triglycerides in relatively short time (6 weeks).

Key words: Dietary supplement, Obesity, Cholesterol, Weight management, Adipose tissue, Triglycerides.

The nature and causes of obesity is the subject of intensive and continuing research. Both environmental and genetic factors are involved in a complex interaction of variables, which include psychological and cultural influences as well as physiologic regulatory mechanisms (1). Obesity can be defined as an excess of adipose tissue or the excessive accumulation of body fat (4). This accumulation of excessive fat is the primary culprit of obesity's harmful effects (3).

North Americans and Puerto Ricans consume about two times as much fat as is considered appropriate (40% vs. 20%), in addition to consuming the wrong types of fat (saturated, trans-fatty acid and excessive Omega 6 fatty acids) (5). This is usually accompanied with a high consumption of simple refined sugar, which adds more calories in addition to providing an optimum biochemical

environment for fat deposition.

Obesity has become a serious problem of health due to its possible consequences such as insulin resistance, diabetes type 2, hypertension and cardiovascular disease (1). Obesity is a major public health concern because it increases morbidity, mortality, psychological problems, discrimination and reduces economic achievement (9). The increasing obesity problem in combination with smoking habits, and minimal or absent physical activity are a truly deadly combination that has been linked to cardiovascular morbidity and mortality, and to certain types of cancer (breast, colon, prostate) (3).

It has been shown that the body fights dieting. When people lose weight through calorie restriction, the rate at which they burn calories-actually slows down (2). This reduction in metabolism is an evolutionary trait. The human body has a natural "survival mechanism" which fights dieting, unless dieters take steps to keep their metabolism working at a high level, it will naturally slow and stay slowed. This means that keeping weight off becomes extremely difficult, even if people continue eating less (2).

There is a great need for physiological research to help define and describe effective adipose tissue loss that may suppress appetite, inhibit or block lipid absorption, and/or increase thermogenesis. Of great interest is the use of

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supplements and nutraceutical products to help create a proper environment or provide a fine metabolic tuning that will facilitate weight/fat reduction goals (6). For this purpose supplements containing fibers, herbs and vitamins will be studied. Recently, the use of a modified diet and adjunctive drug therapy has been used to achieve desirable reductions in body weight and lipid levels (7). At the same time, positive weight and lipid profile results derived from the combination of aerobic exercise, low fat diet, and supplementation has gained scientific and public interest (8). Supplementation with naturally occurring fibers such as chitosan, psyllium, pectin, glucomannan and guar gum are readily available and commonly recommended by physicians and nutritionists to treat mild to moderate hypercholesterolemia (3). Also interest has risen on the use of herbs and vitamins to enhance metabolism; in order to provide an environment conducive to fat loss.

Methods

The target population included overweight and obese (10%-20% above average body weight) adults between 20 to 55 years old, with a BMI equal or greater than 30, all volunteers. The sample consisted of 10 control subjects and 20 experimental subjects. If allergic to shellfish, subjects were excluded. Eligibility weight percentiles were based on The 1993 Metropolitan Height-Weight Tables. Participants received a combination of supplements (high fiber supplement, vitamin, mineral, herb supplement and a metabolic enhancer formula) for a period of 42 days.

This double-blind, placebo controlled study was conducted with 30 mildly to moderately obese subjects. These were divided in 20 experimental subjects and 10 controls (placebo); 17 experimental and 7 control subjects completed the 6 week experimental period. Participants completed a general health questionnaire. Anthropometrical measures such as body weight, height, and percent body fat were taken. Blood tests (fasting) such as CBC and SMA20 were measured at the beginning of the study at 6 weeks after treatment.

Eligible volunteers meeting all inclusion criteria were consented and then randomized to treatment or placebo groups. Baseline measurements of waist, hips, body weight, % body fat, cholesterol and triglycerides were obtained. As a safety measure, a complete blood count test was performed. All measurements were repeated at 42 days (\pm 6 weeks). The participants were encouraged to continue their normal dietary habits (with no calorie reduction or any type of weight reduction regime). Daily dietary food charts were completed by each subject. Compliance with all study-related procedures was strictly monitored. No physical activity was encouraged and

participants were excluded if involved in heavy physical activities such as jogging, sports, and weight lifting.

All subjects were dispensed a combination supplement of vitamins, minerals and herbs (supplement #1). This was taken as follows: 2 capsules with 8 ounces of water in the morning after breakfast. This formula contains Nutraceuticals that may balance synergistically the glucose/insulin system (9). Another supplement combination consisting of a mixed- high fiber dietary supplement (supplement#2) that should be taken as follows: 2 capsules 15 minutes before lunch and supper with 8 ounces of water. It was demonstrated by Nesbitt et al. that this fiber supplement combination significantly enhanced weight loss by lowering fat absorption and inducing satiety (3). Also an amino acid, fatty acid, herb formula (supplement#3), that was taken as follows: 1 in the morning and 1 at night or 30 min. before a light workout. This formula it is a non-stimulant formulation that should complement fat inhibition and glucose management formulas, to increase metabolism without altering the nervous and cardiovascular system. This was a combination supplement system guided to enhance weight loss with minimal side effects. We embarked in this study to evaluate the safety and efficacy of this supplement combination.

The First law of thermodynamics tells us that obesity results from an imbalance between energy expenditure and energy intake. This combination supplement was designed to influence both. The combination supplement consisted of a mixed of minerals, herbs and amino acids that assists metabolism in fat utilization and disposal. (See Table 1)

SUPPLEMENT DESCRIPTION	
Supplement#1 Glucose control	Oral formula designed to control the glucose/insulin system. Contains: Vitamin C, Thiamin, Riboflavin, Niacin, Vitamin B6, Folate, Vitamin B12, Panthotenic Acid, Choline, Inositol, PABA, Calcium, Phosphorus, Chromium, Vanadium, and Herbs: Garcinia cambogia, Gymnema sylvestre, White Kidney Bean extract and Green Tea.
Supplement#2 Fat absorption inhibitor	Mixed fiber supplement containing 51% psyllium, 40% chitosan, 4% glucomannan and 4% pectin.
Supplement#3 Metabolic enhancer	A non-stimulant formula that complements the fat inhibition and carbo control formulas. Contains: B complex, Conjugated linoleic acid, Taurine, Lecithin, Green tea extract, L-carnitine, Inositol phosphate, Ascorbic acid, Ginger extract, Capsaicin.

Statistical Analysis. The data was analyzed using the Statistical Package for the Social Sciences (SPSS version 6.1.1). A Kolmogorov Smirnov Goodness of Fit test was performed on all variables in the experimental group to test the null hypothesis that the data came from a normally distributed population. The results accept the null hypothesis for all variables ($p > 0.05$). Next, a parametric paired-sample t Test was carried out to test the null hypothesis that there is no significant difference between the mean of the initial measurements (i.e., before treatment) and the mean of the final measurement (i.e., post-treatment). This test was performed for each variable included in the experimental group (treated with supplements). All results reject the null hypothesis. The means are significantly different ($p < 0.05$, see Table 2 for details on degrees of freedom, p-values, confidence intervals, and standard error for each variable).

The same hypothesis was tested for the same variables in the control group given placebo. First, a K-S test was also performed as above and the results were the same for all the variables. Next, the paired sample t-Test showed no significant differences in the initial mean (before treatment) and final mean value (post-treatment) for all the variables in the control group. Thus, there was no significant change in the mean value as a result of the placebo effect. Since the control group included only seven subjects, a non-parametric analog to the paired sample t-Test, the Wilcoxon Paired sample test was also performed to corroborate the results of the parametric t Test. Results were the same ($p > 0.05$) for all the variables (see above for information on degrees of freedom, confidence limits, p-values and standard errors for each test).

Results

All measurements were taken twice during the study at the beginning and at 6 weeks of combination supplement treatment or placebo.

Body weight. The average weight loss in the experimental group was -8.59 Lb, while the control group gained an average of +2.14 Lb during the six week experimental period. This difference was found to be statistically significant ($p < 0.001$).

Body fat %. The average % fat in the experimental group was -2.88 %, while the control group gained +0.86 %, this difference was found to be statistically significant ($p < 0.001$).

Waist measurement. The average waist measurement loss was -1.39 in. for the experimental group, while the control group gained +0.42 in., this difference was found to be statistically significant ($p < 0.001$).

Hip measurements. The average hip measurement loss was -0.59 in. in the experimental group, while the measurement of the control group did not change. This difference was found to be statistically significant ($p < 0.001$).

Total cholesterol. The combination supplement treatment group had an average decrease of -22.94 mg/dL in total cholesterol, while the control group had an increase of +2.14 mg/dL. The combination supplement very significantly decreased total cholesterol when compared to placebo in this study ($p < 0.001$).

Triglycerides. The combination supplement treatment group had an average decrease of -39.29 mg/dL in triglycerides, while the control group had a decrease of -0.28 mg/dL. The combination supplement significantly decreased triglycerides when compared to placebo in this study ($p < 0.001$). The small difference among the placebo group (before and after) was not found to be significantly different ($p = 0.182$).

Discussion

This clinical investigation of a combination supplement was undertaken because to date, data available on safety and effectiveness of supplements or combination of these on human weight/fat reduction is lacking. Animal data exists suggesting an important role for fiber supplements such as chitosan, psyllium, pectin and glucomannan in the treatment of obesity (4).

This research was a double-blind, placebo-controlled study for a period of 6 weeks. The primary aims were to test for safety, effectiveness and identify any difference in total body weight, body fat %, hips and waist measurements, total cholesterol and triglycerides. In relation to total body weight, interestingly in a previous report by our group, the average weight loss utilizing just one of the combination supplements (supplement #2, the mixed fiber supplement) was -3.63 Lb. This shows a doubling effect when the synergistic supplements are combined (-8.59 Lb vs. -3.63 Lb) during the six week period. In addition to body weight, body fat %, waist and hips measurements were also reduced significantly. In relation to blood lipids, total cholesterol was reduced -22.94 mg/dL in six weeks. This result doubles the reduction attained in a previous report utilizing a fiber supplement alone (-22.94 mg/dL vs. -11.05 mg/dL). Triglycerides were also significantly lowered.

Patients found combination supplement easy to take and experienced practically no adverse side effects such as insomnia, headaches and irritability often found in other dietary supplements and aids promoted for weight/fat reduction. In addition, this formula does not negatively

affect the nervous or cardiovascular systems. The mechanisms proposed for the effectiveness of this synergistic combination supplement are fairly simple. It provides the building blocks (vitamins, minerals and amino acids) to improve enzyme function thus optimizing physiological metabolism. These extra nutrients seem to correct subclinical deficiencies and metabolic imbalances present in obese people that may prevent or make difficult the physiological changes needed for weight/fat reduction. This orthomolecular approach in the treatment of obesity is a novel idea that if proven, will facilitate its understanding and treatment.

Resumen

Se hizo un estudio doble-ciego, controlado con placebo para evaluar la seguridad y eficacia de un sistema de suplementación nutricional que consiste en una combinación de vitaminas, minerales, hierbas, fibras y amino ácidos en la pérdida de peso y de grasa corporal, colesterol y triglicéridos. El peso corporal total, el % de grasa corporal, las medidas de la cadera y de la cintura, el colesterol total y los triglicéridos fueron evaluados antes y después de seis semanas de tratamiento con la combinación de suplementos o de placebo. La población del estudio consistió de 27 voluntarios con obesidad leve a moderada sin ninguna otra condición. Luego de las seis semanas en el tratamiento, el consumo de la combinación de suplementos tuvo un efecto estadísticamente significativo ($p < 0.001$, $\mu = 0.05$) en la reducción de peso (-8.59 Lb vs. +2.14 Lb). Dicha reducción de peso fue asociada con la correspondiente disminución significativa ($p < 0.001$, $\mu = 0.05$) en el % de grasa corporal en el grupo de tratamiento

(-2.88%) vs. el grupo placebo (+0.86%). También, se obtuvo una reducción significativa en el colesterol total (-22.94 mg/dL) y en los triglicéridos (-39.29 mg/dL) y

disminuyeron además las medidas de la cintura y de la cadera. Estos resultados positivos nos llevan a concluir que la combinación de suplementos dietarios estudiada es una forma saludable y efectiva para ayudar en la reducción de peso y de grasa, además de que disminuye el colesterol total y los triglicéridos en un periodo relativamente corto (6 semanas).

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