

# Effect of a short term dietary supplement combination program on weight management, adipose tissue, cholesterol and triglycerides in overweight adults.

A Medical University Research Study done on thirty-five overweight adults taking the NuLean Wellness Weight-Loss Cleanse revealed that after seven days:

- The average person lost 7.5 pounds.
- The average combined total inches lost per person (waist, chest, hips abdomen) was 7.63 inches.
  - Average glucose measurement per person dropped by 3.7%
    - Reduction in body fat was 3.02%.
  - Average total cholesterol per person dropped by 5%.
  - Average loss in triglycerides per person was 19.3%.

## Director of the study, Michael J. Gonzalez, M.D., stated:

“This dietary intervention program had no negative side effects, compliance was excellent (90%). A point of discussion is how can this short-term program can be effective. We believe it is due to metabolic correction and systemic detoxification. Metabolic-correction caused by the combination of supplements in the diet that provide the necessary building blocks to improve enzyme function. Thus, correcting and optimizing metabolism. "These nutrients seem to correct sub-clinical deficiencies and metabolic imbalances probably due to a faulty diet consisting of empty calories that lack nutrients and fiber. Also a faulty diet contains additives, processed material that may provide a toxic environment that may prevent or make difficult, the physiological changes necessary to achieve weight/ fat loss and at the same time assist normal physiological functions. The dietary supplement program presented herein resulted as a safe and effective short-term way to achieve weight loss, reduce body fat, and improve lipid profile.”

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## Abstract

A dietary supplement combination program (NuLean Liquid Cleanse + NuLean Protein Powder) consisting of liquid supplement and a protein shake was studied to determine its safety and efficacy on weight/fat loss, cholesterol and triglycerides levels in thirty five overweight adults between ages 14-60. This open label trail measured total body weight, body fat percentage, waist circumference, hips (females), chest (females), abdomen (males), glucose, total cholesterol and triglycerides before and after one week on the dietary program. A group of thirteen subjects continued on the dietary program for one more week and anthropometric measures were obtained. Interestingly after only one week on the dietary supplement program the subjects experience a statistically significant ( $p < 0.05$ ) weight reducing effect. This weight reduction was accompanied with a corresponding statistically significant ( $p < 0.05$ ) decrease in body fat percentage. In addition significant decrease in total cholesterol ( $p < 0.05$ ) and triglycerides ( $p < 0.01$ ) resulted. Also reduction in waist, hip and chest measurements were obtained. We conclude that the dietary supplement combination program studied herein is a safe and effective way to assist adults in weight, fat, cholesterol and triglyceride reduction.

## Introduction

The public health problem of obesity and unhealthy weight gain has grown considerably in the United States and Puerto Rico in recent years (1). We know this is a chronic disease that involves complex interactions among genetics, environmental, cultural and behavioral factors. Positive energy balance is required in order for weight gain to occur. In other words energy intake must exceed energy expenditure. Obesity is among the easiest medical conditions to diagnose, but most difficult to treat. The annual cost to society for obesity is estimated to be at nearly \$ 100 billion/ year (2). Moreover, unhealthy weight gain is responsible for over 300,000 deaths/ year (3).

Obesity has serious health consequences that have a disproportionate effect on minorities, women, children, the aged population, and those in lower socioeconomic status. Obesity is associated with type II diabetes mellitus, it increases the risk for coronary heart disease, osteoarthritis, cancer, and stroke (4). We embarked in this study to evaluate the safety and efficacy of this short term dietary supplement program for weight/ fat loss.

## **Methods**

The target subjects included overweight and obese (10% and above average body weight with a body mass index (BMI) over 25. All volunteers living in Ponce, Puerto Rico. The study sample consisted of 35 experimental subjects for the first week and 13 follow up experimental subjects for the second week those consisted of 22 females and 13 males between the ages of 14-60. in the first group and 13 subjects that decided to continue the diet for one more week (10 females and 3 males) in the second group. All participants completed a general health questionnaire and anthropological measures such as body weight, height, percent body fat, waist, hip, and chest measurements. Blood tests (fasting) such as CBC and SMA 20 were taken at the beginning of the study and a week after treatment. Eligible volunteers meeting all inclusion criteria who consented were included in the study and provided with the supplements. The participants received two dietary supplement to be utilized for a week as part of the experimental program. They received a protein shake mix and a liquid supplement to be used in the following manner: a protein shake mix consisting of 16g of protein, 1g of fat, 1g of sugar, 2g of fiber and an enzyme mixture. This shake is taken two times a day to replace breakfast and lunch (a scoop 24 g is added to water or skim milk. The second supplement is a liquid juice, consisted of a mixture of juices with aloe and pomegranate and mixture of botanical extracts that included Ginseng, Green tea, Guarana, Gymnema silvestre, Garcinia cambodia, Yerba mate, Cascara sagrada, and with a mixture of additional vitamins and minerals, (B complex, vitamin C and chromium). The participants were encouraged to continue their normal lifestyle with no other weight reduction regime other than the experimental program. Compliance with all study related procedures were strictly monitored. All subjects dispensed with enough supplement for a week of use.

## **Statistical Analysis**

The data was analyzed using the statistical package SPSS version 12. 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 accepted the null hypothesis for all variables ( $p < 0.05$ ). Next a parametric paired-sample t-test was carried out to determine that there is no significant difference between the mean of the initial measurements (i.e. before treatment) and the mean of the subsequent measurements (i.e post-treatment). This test was performed for each variable included in the experimental group (treated with the dietary program). All results rejected the null hypothesis and the means were significantly different ( $p < 0.05$ ). Also an analysis of variance was performed between the three measurements resulting in a significant difference ( $p < 0.05$ ) among the three measurements. Finally, a Pearson coefficient was calculated to test the degree of correlation in the change detected between the pre and post-treatments. All results showed a significant coefficient ( $p < 0.05$ ) consistent with the changes observed experimentally.

## Results

All measurements reported on the 36 subjects were taken twice during the study (at the beginning and at 7 days of dietary treatment) another measurements were taken on the 13 subjects that continued treatment for one more week. All subjects served as their own controls.

**Total body weight:** The average weight loss was 7.5 lb.  $\pm$  2.30 during one week of dietary treatment. The mean  $\pm$  SE per body weight at the beginning of the study was 198.34 lb.  $\pm$  6.68 and at the end of the week was 190.89 lb.  $\pm$  6.21. This difference was found to be statistically significant ( $p < 0.05$ ). In the 13 subjects that continued the dietary program for 1 more week their mean body weight after the treatment was 180.52 lb.  $\pm$  5.51 (their mean body weight before second treatment was 188.55 lb.  $\pm$  4.87)

**Body Fat Percentage:** The average % fat loss was 3.02%  $\pm$  0.99. The mean  $\pm$  SE for body fat % at the beginning of the study was 39.61%  $\pm$  1.07 and at the end was 36.59%  $\pm$  1.01. This difference was found to be significant ( $p < 0.05$ ). In the subjects that extended their treatment for one more week the mean body fat percentage was 33.01%  $\pm$  0.98 (The man body fat percentage before the second treatment was 36.20%  $\pm$  1.01)

**Waist measurement:** The average waist measurement loss was 2.32 in  $\pm$  0.81. The waist measurement at the beginning was 40.046 in  $\pm$  1.03 and at the end 38.14 in  $\pm$  0.99. This difference was found to be significant ( $p < 0.05$ ). The subjects that followed treatment for one more week the mean waist measurement was 36.25 in  $\pm$  1.01 (Their mean measurement before the second treatment was 38.29 in  $\pm$  1.01).

**Hips measurement:** This measurement was just taken on females. The average hip measurement loss was 2.80 in  $\pm$  1.05. The mean hip measurement at the beginning was 44.89 in  $\pm$  1.07 and at the end of the first week 42.09 in  $\pm$  1.00. In the subjects that had an extra week of the treatment the mean was 40.20 in  $\pm$  0.99. These differences were found to be statistically significant ( $p < 0.05$ ).

**Chest measurement:** This measurement was also taken just on female subjects. The average chest measurement at the beginning of the study was 42.04 in  $\pm$  1.08 and at the end 40.11 in  $\pm$  1.07. In the subjects that furthered their treatment for a week the mean was 37.98 in  $\pm$  1.05. These differences were statistically significant ( $p < 0.05$ ).

**Abdomen measurement:** The measurement was done only on male subjects. The average loss on abdomen measurement was 2.45 in  $\pm$  0.99. The abdomen measurement at the beginning of the study was 44.00 in  $\pm$  1.02 and at the end 41.66 in  $\pm$  0.88. For the group that had an extra week of treatment the average measurement was 38.42 in  $\pm$  0.90. These differences were found to be statistically significant.

**Glucose** Glucose measurement at the beginning of the study was 84.99 mg/dL  $\pm$  1.47 and at the end 81.82 mg/dL  $\pm$  1.43. For the group that had an extra week of treatment was 80.75  $\pm$  1.45. Here a tendency toward reduction was attained but only statistical difference was obtained for the pretreatment vs. post treatment values ( $p < 0.05$ ).

**Total cholesterol:** The average loss of total cholesterol was  $5 \text{ mg/dL} \pm 5.25$ . The total cholesterol at the beginning was  $186.32 \text{ mg/dL} \pm 7.85$  and at the end  $181.32 \text{ mg/dL} \pm 0.81$ . For the group that had an extra week of treatment was  $180.37 \text{ mg/dL} \pm 4.55$ . These differences did not result in a statistical difference. Nevertheless, when we separate the subjects that had total cholesterol over 200 from the rest of the group (14 subjects) their total cholesterol at the beginning was  $237.5 \text{ mg/dL} \pm 5.51$  and at the end it was  $211.05 \text{ mg/dL} \pm 5.25$  which resulted in a statistically significant difference ( $p < 0.01$ ).

**Triglycerides:** The average loss in triglyceride value was  $22.31 \text{ mg/dL} \pm 7.01$ . The triglyceride level at the beginning of the study was  $115.25 \text{ mg/dL} \pm 9.52$  and the end was  $92.94 \text{ mg/dL} \pm 7.09$ . The triglyceride level for the subject that had an extra week of treatment was  $80.37 \text{ mg/dL} \pm 6.99$ . These differences had a statistical significance ( $p < 0.05$ ).

## Discussion

This clinical investigation utilizing a short term dietary supplement program for weight/fat loss was undertaken because to date data available on safety and efficacy of short term dietary supplement programs such as these are lacking. Most short term “fad” diets may produce weight loss by means of solely water loss with no fat loss. This research was an open label experimental clinical trial in which subjects served as their own control for a period of one week and a subset for another additional week. The primary aim of the research was to test for safety and the secondary aim was to test for effectiveness by identifying any changes in total body weight, body fat percentage, waist, hips, chest measurements as well as glucose, total cholesterol and triglycerides. In relation to total body weight, we achieved a significant reduction in only seven days on the program. Moreover, body fat percentage was significantly reduced during that short period. These results demonstrated in part that weight loss was due to fat loss instead of only water content or muscle loss. Waist, hips, abdomen, and chest measurements were also significantly reduced. These results are of great importance to the subjects since the loss of fat inches is what they perceive as success rather than just the loss of weight. Also 90% of the subjects reported reduce appetite and more energy while in the program. There was a tendency of reduction of fasting blood glucose but did not reach statistical significance although we should mention that fasting blood glucose in the subjects at the start of the study were within normal ranges. The only statistical difference was obtained when comparing pre-treatment vs. post-treatment. We should state this difference was within normal ranges as stated earlier and seems to lack any physiological significance or to have any biological impact. Nevertheless, it would be interesting to do a similar study with subjects having glucose/ insulin problems (syndrome X, diabetes, etc.).

In relation to total cholesterol, there was a tendency toward reduction that did not reached statistical significance. Although it should be pointed out that total cholesterol value for this sample was within normal ranges. But when we separate the subjects with total cholesterol values of over 200 their mean total cholesterol value was  $237.5 \text{ mg/dl} \pm 5.51$  and at one week after treatment lowered to  $211.05 \text{ mg/dl} \pm 5.25$  which resulted in a statistically significant difference ( $p < 0.01$ ). In relation to triglycerides these reduced significantly after one week of the dietary treatment program.

This dietary intervention program had no negative side effects, compliance was excellent (90%). A point of discussion is how can this short term program be effective. We believe is due to metabolic correction and systemic detoxification. Metabolic correction refers to the combination of supplement regime that provides the necessary building blocks to improve enzyme function. Thus, correcting and optimizing metabolism. These nutrients seem to correct subclinical deficiencies and metabolic imbalances probably due to a faulty diet consisting of empty calories that lack nutrients and fiber. Also a faulty diet contains additives, processed material that may provide a toxic environment that may prevent or make difficult, the physiological changes necessary to achieve weight/ fat loss and at the same time assist normal physiological functions. The dietary supplement program presented herein resulted as a safe and effective short term way to achieve weight loss, reduce body fat, and improve lipid profile.

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### **References**

- Gonzalez MJ, Miranda-Massari JR, Ricart CM. **Effect of a dietary supplement combination on weight management, adipose tissue, cholesterol and triglyceride in obese subjects.** *PR Health Sci J* 2004,23:121-124.
- Wellman NS, Friedberg B. **Causes and consequences of adult obesity: health, social, and economic impact in the United States.** *Asia Pac J Clin Nutr* 2002,(58):5701-709.
- Stern CJ, Colditz GA. **The epidemic of obesity.** *J Clin Endocrinol Metab* 2004,89:2522-2525.
- World Health Organization: **Obesity: Prevention and managing the global epidemic.** *Report of Who consultation on obesity.* Geneva; World Health Organization 1997

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