

CLINICAL STUDIES



The safety and effectiveness of the exclusive formula used in Dr. Agin's Skinny D nutrient concentrate has been studied in three clinical trials.

CLINICAL STUDY 1

The purpose of the first medical study was to see if using Skinny D together with a strict reduction in two of the three meals per day would produce safe and effective results after only one week. The results showed a significant loss of weight and reduction in body measurements, as well as improvements in several blood values:

Weight loss: 7.5 lbs	Body fat percentage reduction: 3.02%
Waist size reduction: 2.32 inches	Hips size reduction: 2.80 inches
Chest size reduction: 1.93 inches	Abdomen size reduction: 2.45 inches
Glucose reduction: 3.17 mg/dL	Total cholesterol reduction: 5 mg/dL
	Triglycerides reduction: 22.31 mg/dL

HOW DOES IT WORK?

The researchers named the items below as likely reasons for the effectiveness of the ingredients in the Skinny D:

1. Replacing a meal with the nutrient concentrate reduces the intake of calories and cholesterol.
2. The nutrient concentrate provides such a high degree of overall nutrition that the participants experienced no cravings for food.
3. Specific constituents in the nutrient concentrate may directly reduce appetite.
4. Some plant compounds in the nutrient concentrate may safely modulate expression of genes involved in lipid (fat) metabolism.

CLINICAL STUDY 2

The second study was carried out to see if a dieter could comfortably use this nutrient concentrate for a longer period of time than one week (four weeks) without secondary effects such as tiredness and hunger feelings. The dietary restrictions were not as strict as in the previous study: One meal per day was replaced by the nutrient concentrate.

Weight loss: 7.48 lbs	Waist size reduction: 2.75 inches
Hips size reduction: 2.32 inches	Chest size reduction: 2.56 inches

An observation from this study was that the greater the starting weight of a participant, the greater was the weight lost. Some obese participants lost over 20 pounds during the trial.

CLINICAL STUDY 3

The third trial was made to see if the nutrient concentrate could improve lipid (fat) metabolism at a very early stage of being overweight. This study also had no dietary modifications other than using the nutrient concentrate in lieu of breakfast.

Weight loss: 4% (5.72 lbs)	Waist size reduction: 5.4% (1.73in)
Buttocks size reduction: 2.6% (.94 in)	Rump size reduction: 3.2% (1.18in)
Blood pressure reduction: 1.6%	Total cholesterol reduction: 4.7%
LDL cholesterol reduction: 2.0 %	Triglycerides reduction: 29.5%
Blood glucose reduction: 12.1%	Insulin reduction: 12.6%

Effect of a short term nutrient concentrate program on weight management, adipose tissue, cholesterol and triglycerides in overweight adults.

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Abstract

A nutrient concentrate consisting of a liquid supplement and a protein supplement (manufactured by Nutrition Laboratories, Inc. of Florida, USA) 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 concentrate. A group of thirteen subjects continued on the concentrate for one more week and anthropometric measures were obtained. Interestingly after only one week on the 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 nutrient concentrate and protein supplement 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 in recent years (1). We know this is a chronic disease that involves complex interactions among genetics, environmental, cultural and behavioral factors. A 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). 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 a liquid nutrient concentrate to be utilized for a week as part of the experimental program. This product consisted of a blend of of juices including aloe and pomegranate and mixture of botanical tea extracts that included Ginseng, Green tea, Gymnema silvestre, Garcinia cambodia, Yerba mate, Cascara sagrada, plus a mixture of additional vitamins and minerals, (B complex, Vitamin C and Chromium). For the purpose of controlling the calorie intake during the study and ensure that the participants a balanced diet, they also received a protein shake consisting of 16g of protein, 1g of fat, 1g of sugar, 2g of fiber and an enzyme mixture per serving. The participants were recommended to take the protein shake twice a day with skim milk as breakfast and lunch. The participants were encouraged to do some form of daily exercise, such as a half hour walk. They were otherwise instructed 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 concentrate and protein for a week of use.

Statistical analysis

The data was analyzed using the statistical package SPSS version 12. A Kolmogorov-Smirnoff 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 posttreatment). 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 only 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 mg/dL \pm 5.25. The total cholesterol at the beginning was 186.32mg/dL \pm 7.85 and at the end 181.32 mg/dL \pm 0.81. For the group that had an extra week of treatment was 180.37 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 mg/ dL \pm 5.51 and at the end it was 211.05 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 mg/dL \pm 7.01. The triglyceride level at the beginning of the study was 115.25 mg/dL \pm 9.52 and the end was 92.94 mg/dL \pm 7.09. The triglyceride level for the subject that had an extra week of treatment was 80.37 mg/dL \pm 6.99. These differences had a statistical significance ($p < 0.05$).

Discussion

This clinical investigation utilizing a short term nutrient concentrate and protein supplement program for weight/fat loss was undertaken because to date data available on safety and efficacy of such programs are lacking. Most short term “fad” diets may produce weight loss by means of solely water loss with no measurable 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 the program 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 body 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 reach statistical significance. Although it should be pointed out that total cholesterol value for this sample population 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 mg/dl \pm 5.51 and at one week after treatment lowered to 211.05 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 on 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 a combination nutrients that provides the necessary building blocks or cofactors 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 the necessary 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 and metabolic alignment to achieve weight/ fat loss and at the same time assist normal physiological functions. The dietary supplement program presented herein resulted in a safe and effective short term way to achieve weight loss, reduce body fat and improve lipid profile.

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