The effects of a 6-week weight management program, utilizing non-pharmaceutical nutritional supplements, on weight reduction, subjective energy level, cholesterol, triglycerides, adipose tissue and liver enzymes in obese adults.

Dr. Gerald W. Lane, Medical Director & Primary Research Investigator
Institute for Metabolic Research, Columbus, Ohio

Dr. Lane is Administrative Director of Research at The Institute for Metabolic Research, Columbus, Ohio. He is a graduate of Ohio University College of Osteopathic Medicine, Athens, Ohio. He is former Medical Director for Hilltop Research and Radiant Research, Columbus Ohio. Dr. Lane has contributed toward greater than 250 clinical research projects over 15 years. Past Clinical Associate Professor of Medicine, Ohio University, College of Osteopathic Medicine, Athens, Ohio

Direct correspondence to: Dr. Gerald Lane, email: ifmresearch@aol.com

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Abstract

A nutritional supplement program studied 35 participants to determine safety and efficacy of the products (a liquid nutrient concentrate) while measuring weight reduction, lipids, adipose tissue and liver enzymes over a 6 week period. This was an open label trial with obese adults which measured total weight, percentage of body fat, andropometric measurements of mid-arm circumference, abdomen, hips, thighs, caliper measurements of skin folds of triceps, supraliac and mid-thigh (female) and caliper measurements of skin folds of chest, abdomen and mid- thigh (males), electrolytes, glucose, cholesterol, triglycerides, albumen, total protein, bilirubin, BUN, Creatinine, SGOT, SGPT, and subjective energy levels (self reported by participants).
The group participated in a 72 hour program utilizing only the nutritional supplements and hydration. The results were remarkable. Every subject in the program lost weight with an average weight loss of 8.7 pounds. They then continued to utilize the nutritional products to replace one meal per day for 39 additional days. The average weight loss after 14 days was 18.2 pounds and 28.4 pounds at the conclusion of the 6 week trial.

Patient's metabolic functions were closely monitored in order to document therapeutic benefit, while monitoring for potential side effects. Total cholesterol was lowered in all participants (ave. reduction = 20.6) and every participant with clinically elevated cholesterol (≥ 200) at baseline, reported normal values after 6 weeks. Similarly, all participants with fasting hyperglycemia (s. glu. ≥ 100) returned to normal by the end of the study. This included 3 patients with NIDDM who were not well controlled prior to the study. There was no evidence of hypoglycemia (s. glu. ≤ 65). Participants with elevated liver enzymes at baseline reported normal SGOT & SGPT levels after 2 weeks. No participant developed liver enzyme elevations. Subjective energy level of the participants was reported at baseline as low to average and reported as high to very high at the conclusion of the study. All participants lost total adipose tissue with the average change calculated at 6.7% lost. Decrease in total inches of body fat paralleled that of weight. For each pound of weight lost, the participants lost 0.82" off of body measurements.

Introduction

Obesity is the number one contributor to the development of heart disease, diabetes mellitus and atherosclerosis in developed countries. The toll on human existence, both medically and economically is immense. While we cannot alter genetic factors contributing to obesity, cholesterol and triglycerides and diabetes, we can successfully address the exogenous contribution to these disease states.

Pharmaceutical attempts to promote weight loss have historically been accomplished via appetite suppressants that many times are addictive and or have cardiovascular side effects. The prescribing patterns of these medications are closely monitored by the board of pharmacy in most states, due to abuse and miss-use by patients and prescribers. This study was conducted to document scientifically an effective and safe mechanism to help obese individuals lose weight. The results of this study bear out that there are safe, effective adjuncts to weight loss without the need for prescription medication or frequent physician visits.

Methods

Inclusion in the study required that all subjects were obese adults, between the age 18 and 65, whose weight was at least 15% over IBW (ideal body weight). IBW for males was calculated utilizing the formula: 106# for the first 60" of height and 6 # for each additional inch, plus or minus 6#'s. Females utilize the formula: 100# for the first 60" and 5# for each additional inch, plus or minus 5#'s. **Examples**: a male 5' 8" (68") would have an IBW of 148-160. A female of 5'8" (68") would have an IBW of 135-145. Study participants would be equal or greater than 15% more than the upper limit of the IBW range. The male in the above example would have to weigh ≥ 184 (15% greater than 160) and the female would have to weigh ≥ 167 (15% greater than 145). The study sample consisted of 35 qualified and consented subjects, 2 females and 8 males. The average percentage over IBW was 21% (range of 15% - 45%).

The first study participant was enrolled on August 22, 2010. All participants received a general

physical exam, anthropological body measurements utilizing the Jackson – Pollock scale. This included weight, body circumference measurements of arms, abdomen, hips and thighs plus body fat analysis with caliper measurements of arms, sacroiliac and thigh in females and chest, abdomen and thigh in males. Laboratory analysis included comprehensive metabolic panel + lipids at baseline visit, day 15 and upon conclusion of the study (day 42). On the first visit, the participants were started on the phase one of the study, which consisted of 3 dietary cleansers on day zero and the study products and protocol for days 1-3 (appendix 1 –phase 1). They returned on day 4, weighed, all measurements were repeated and they received the study products and protocol for days 4-42 (appendix 2 – phase 2). On days 15 and 42, they were seen for a follow up visit. Weight, body measurements and labs were repeated.

All data was collected and the study was closed on November 15th, 2010.

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 ($p < 0.01$). 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 ($p < 0.01$) 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 ($p< 0.01$) consistent with the changes observed experimentally.

Results

All measurements reported on the 35 subjects were taken 3 times during the study (at randomization day #1, day #14 and at the conclusion of the study, day #42). All subjects served as their own controls.

Total body weight: Every subject in the program lost weight with an average weight loss of 8.7 (± 2.1) pounds. They then continued to utilize the nutritional products to replace one meal per day for 39 additional days. The average weight loss after 14 days was 18.2 (± 3.7) pounds and 28.4 (± 6.5) pounds at the conclusion of the 6 week trial. This was found to be statistically significant ($p<.01$)

Adipose Tissue: The average % loss of adipose tissue was 6.7% (± 0.8). This difference was found to be significant
($p < 0.01$).

Glucose: The average serum glucose at baseline was 93.76 mg/dL ± 1.89. Glucose at day 14

was 89.55 (± 1.80) and 92 (± 1.54) at the conclusion of 6 weeks. These numbers were not statistically significant. 3 participants with clinically significant hyperglycemia (fasting glucose ≥ 100) had normal values at the conclusion of the study. Of these 3 subjects, the baseline fasting glucose was 154.33 (± 22.67 mg/dL). These 3 subjects fasting glucose on day 42 was 94 (± 2.33 mg/dL). These findings were not statistically significant, however, clinically very revealing.

Total cholesterol: The average loss of total cholesterol was 20.6 mg/dL (± 6.23). The total cholesterol at baseline was 192.2 mg/dL (± 8.05) and at day 42, was 171.6 mg/dL (± 5.67). This was found to be a statistically significant difference ($p<0.01$).

Triglycerides: The average loss in triglycerides was 18.3 mg/dL (± 4.22) for 34 of the 35 patients. This difference had a statistical significance ($p<0.05$).

Of particular interest was one participant whose baseline triglyceride was 1430 mg/dL (normal ≤ 149 mg/dL). The subject was notified of the "alert" values and was offered to be more closely monitored and to be referred to an independent physician for further evaluation. He chose to remain in the study. At day 14 his triglyceride level was reduced to 894 mg/dL, at day 28 was reduced to 782 mg/dL and at day 42 was reduced to 593 mg/dL. He experienced a reduction of 837 mg/dL of his triglycerides. This outlier is scientifically interesting, although not significantly significant. Upon conclusion of the study, he agreed to continue to remain on the study product and agreed to monitor of his triglycerides every 3 months.

Discussion

This study was an open label clinical trial in which subjects served as their own control for a period of 6 weeks (42 days). The primary end points of the research were to assess the efficacy of a non-pharmacological weight loss system while monitoring for safety. Secondary end points were to demonstrate if the studied products would elucidate medically therapeutic changes in fasting glucose, cholesterol and triglycerides while monitoring hepatic and renal functions for safety.

Each subject was monitored for changes in total body weight, percentage of adipose tissue (total body fat), waist, hips, chest measurements as well as glucose, SGOT, SGPT, albumin, total cholesterol and triglycerides.

Significant reductions were found in total weight loss, total body adipose tissue, cholesterol and triglycerides while participants experienced no clinically significant adverse effects. There were no elevations in hepatic function studies and participants experienced normalization in SGOT, SGPT if those values were elevated at baseline. Likewise, there were 3 participants with elevated fasting glucose at baseline. These 3 participants had normalization of their fasting glucose upon conclusion of the study, while there were no subjects who experienced hypoglycemia. All subjects reported stable serum albumin levels as documentation maintenance of proper nutritional balance.