

NUTRITION

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

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A dietary supplement combination consisting of vitamins, minerals and fibers was studied to determine its safety and efficacy on weight/fat loss, cholesterol and triglycerides in children between ages 7-13. This open label trial measured total body weight, body fat percentage, waist circumference, total cholesterol, triglycerides before and after 6 weeks of treatment. The study population consisted of 25 mildly to moderate obese, otherwise healthy children of both sexes. After 6 weeks of treatment, the combination supplement had a statistically significant ($p < 0.05$)

weight reducing effect. This weight reduction was associated with a corresponding statistically significant ($p < 0.0001$) decrease in body fat percentage. In addition, significant decreases in total cholesterol ($p < 0.0001$) and triglycerides ($p < 0.0001$) were obtained, plus reductions in waist measurements. We conclude that the combination supplement studied herein is a safe and effective way to assist children in weight, fat percentage, cholesterol and triglyceride reduction.

Keywords: Dietary supplement, Childhood obesity, Cholesterol, Weight management

The problem of childhood obesity in the United States and Puerto Rico has grown considerably in recent years. Between 16 and 33 % of children and adolescents are obese (1). Obesity is among the easiest medical conditions to be recognized and diagnosed, but most difficult to treat. The annual cost to society for obesity is estimated at nearly \$100 billion (2). Moreover, unhealthy weight gain is responsible for over 300,000 deaths a year (3), and overweight children are much more likely to become overweight adults (4).

The causes of obesity are complex and include genetic, biological, behavioral and cultural factors. In general, obesity occurs when a person eats more calories than the body burns up. Examples are: excessive time spent watching television, using the computer and playing video games is partly to blame for these escalating trend in childhood obesity. Children on average, spend up to six

hours a day involved in these sedentary activities. To make matters worse, children are influenced with well-crafted TV ads from fast food chains and other purveyors of high fat, high sugar meals and snacks. These highly effective advertising campaigns, combined with a physically inactive lifestyle, have produced a generation of kids who are at high risk for obesity-associated medical conditions.

Obesity presents numerous problems for the child. In addition to increasing the risk of obesity in adulthood, childhood obesity is the leading cause of pediatric hypertension. Also it is associated with type II diabetes mellitus. It increases the risk of coronary heart disease stress on the weight-bearing joints predisposing them to osteoarthritis. It lowers self-esteem and affects relationship with peers. Social and psychological problems are significant consequences of obesity in children.

The treatment of childhood obesity is difficult. Most programs are aimed to slow or halt weight gain instead of weight loss as a goal.

Methods

The target population included overweight and obese (10%-20% above average body weight) children (10 males, 15 females) between 7-13 years old, with a body mass index (BMI) equal or greater than 30, all volunteers

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attending the private school Colegio Ave María in Ponce, Puerto Rico. The study sample consisted of 25 experimental those subjects allergic to shellfish were excluded.

The participants received two supplements (a multivitamin mineral formula and a high fiber supplement) that should be taken for 45 days. All participants completed a general health questionnaire and anthropometrical measures such as body weight, height, percent body fat and waist measurement were taken. Blood tests (fasting) such as CBC and SMA20 were defined at the beginning of the study and 6 weeks after treatment was started. Eligible volunteers meeting all inclusion criteria who consented were included in the study and provided with the supplements.

The participants were encouraged to continue their normal lifestyle and dietary habits (with no calorie reduction or any type of weight reduction regime other than the supplement). Daily dietary food charts were completed for 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, aerobics, active sports or weight lifting. All subjects were dispensed two supplement bottles, one of vitamin-mineral combination (supplement 1) and two of a mixed high fiber supplement (supplement 2). These were taken as follows: one vitamin-mineral capsule in the morning with breakfast; two fiber capsules taken 15 minutes before lunch and dinner with 8 ounces of water. A similar combination fiber supplement was demonstrated by Nesbitt, et al. to significantly enhance weight loss in adults by lowering fat absorption and inducing satiety (5). This vitamin-mineral-fiber combination supplement system was guided to assist weight loss with minimal side effects. We embarked in this study to evaluate the safety and efficacy of this supplement combination in childhood obesity.

Statistical analysis. The data was analyzed using the statistical package for the social sciences (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 accept 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 final measurement (i.e., post-treatment). This test was performed for each variable included in the experimental group (treated with supplements). All results rejected the null hypothesis and the means are significantly different ($p < 0.05$). Finally, a Pearson coefficient was calculated to

test the degree of correlation in the change detected between the pre and post-treatment. All results showed a significant coefficient ($p < 0.05$) consistent with the change observed between pre and post-treatment.

Results

All measurements reported were taken twice during the study, at the beginning and at 6 weeks of supplement treatment. All subjects served as their own controls.

Body weight. The average weight loss was $5.80 \text{ lb} \pm 2.32$ during the six week experimental period. The mean \pm SE for body weight at the beginning was $122.60 \text{ lb} \pm 5.53$ and at the end it was $116.80 \text{ lb} \pm 5.53$. This difference was found to be statistically significant ($p < 0.05$).

Body fat percentage. The average % fat loss was $4.68 \% \pm 0.29$. The mean \pm SE for body fat % at the beginning was $34.80 \% \pm 1.28$ and at the end was $30.12 \% \pm 1.21$. This difference was found to be statistically significant ($p < 0.0001$).

Waist measurement. The average waist measurement loss was $2.32 \text{ in} \pm 0.22$. The waist measurement at the beginning was $33.84 \text{ in} \pm 0.77$ and at the end $31.52 \text{ in} \pm 0.75$. This difference was found to be statistically significant ($p < 0.005$).

Total cholesterol. The average loss in total cholesterol was $21.38 \text{ mg/dL} \pm 3.06$. The total cholesterol at the beginning was $179.52 \text{ mg/dL} \pm 6.70$ and at the end $158.14 \text{ mg/dL} \pm 5.31$. This difference was found to be significant ($p < 0.0001$).

Triglycerides. The average loss in triglycerides was $19.95 \text{ mg/dL} \pm 3.02$. The triglyceride level at the beginning was $109.00 \text{ mg/dL} \pm 12.75$ and at the end $89.05 \text{ mg/dL} \pm 10.86$. This difference was also found to be significant ($p < 0.0001$).

Discussion

This clinical investigation of a combination supplement for childhood weight loss was undertaken because to date, data available on safety and effectiveness of supplements or combination of these is lacking. Animal data is available suggesting an important role for vitamins and minerals correcting metabolism to assist weight loss and with fibers as a treatment for obesity (7).

This research was an open-label experimental clinical trial in which subjects served as their own controls for a period of six weeks. The primary aims were to test for safety, effectiveness and to identify any changes in total body weight, body fat percentage, waist measurements, total cholesterol and triglycerides. In relation to total body weight, we achieved a significant reduction in only 45

days with this vitamin-mineral-fiber combination supplement. In addition, body fat percentage was significantly reduced, showing that most of the weight loss was due to fat loss and not water content nor muscle. Waist measurements were also reduced. This is an area where fat tends to concentrate in children. Total cholesterol and triglycerides were also very significantly reduced, thus, reducing two of the most common cardiovascular risk factors and the patients experienced no adverse side effects. Moreover, this combination had no negative effects on the nervous or cardiovascular systems. The mechanism proposed for this vitamin-mineral-fiber combination supplement is relatively simple; in addition to the well recognized binding capacity of the fiber, the vitamins and minerals provide the building blocks to improve enzyme function, thus optimizing physiological metabolism. These nutrients seem to correct subclinical deficiencies and metabolic imbalances that may be present in obese children probably due by a faulty diet consisting of many empty calories that lack nutrients and fiber. That may prevent or make difficult the physiological changes needed for weight/fat reduction and at the same time to assist in normal physiological functions and growth. The treatment presented herein resulted in a safe and effective way to achieve weight loss, reduce body fat and improve lipid profile.

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Resumen

Se estudió un suplemento nutricional que consiste de vitaminas, minerales y fibras para determinar su seguridad

y eficacia en pérdida de peso, nivel de colesterol y triglicéridos en niños entre las edades de siete a trece años. En este estudio se midió el porcentaje de grasa corporal, la circunferencia de la cintura, el colesterol total, y el nivel de triglicéridos en sangre al comienzo del estudio y luego de seis semanas de tratamiento. La población estudiada consistió de 25 niños de ambos sexos, moderadamente obesos, pero sin ninguna otra condición. Luego de seis semanas de tratamiento, el grupo usando el suplemento de combinación demostró una reducción en peso estadísticamente significativa ($p < 0.05$). Esta reducción en peso se asoció con una disminución en el porcentaje de grasa estadísticamente significativa ($p < 0.0001$). Además, se obtuvieron reducciones significativas en colesterol total ($p < 0.0001$) y triglicéridos ($p < 0.0001$) así como en la reducción de las medidas de circunferencia de cintura ($p < 0.05$). Estos resultados nos hacen concluir que el suplemento de combinación estudiado es una manera segura y efectiva de ayudar a los niños a reducir peso, grasa corporal, colesterol total y triglicéridos.

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