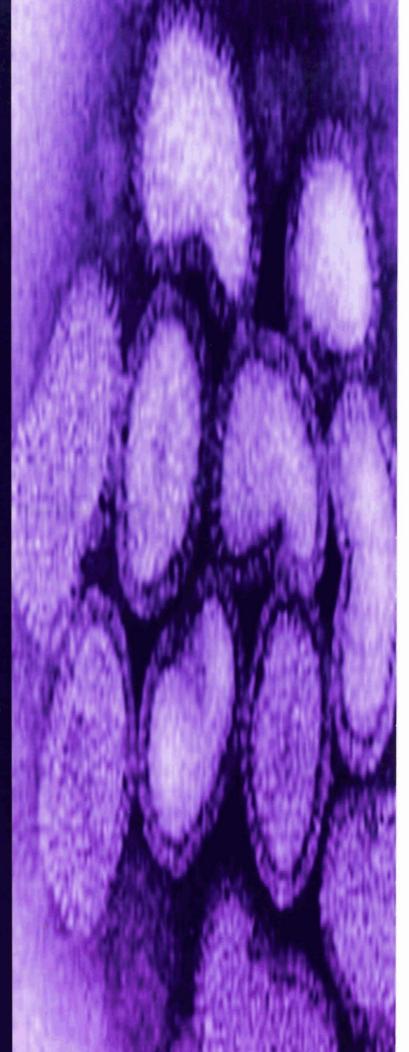
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ABSTRACT

Often Chronic Fatigue Syndrome (CFS) patients have weight issues, and weight reduction regimens can increase fatigue. Therefore, we initiated a weight loss clinical trial using an all natural oral supplement mixture containing an FDA-approved amaylase inhibitor plus NTFactorTM, which is known to safely reduce fatigue in aged subjects,1 chronic fatigue2 and CFS.3 The objective was to see if subjects could safely lose weight without increasing appetite and fatigue and without changing eating or exercise patterns or using drugs, herbs or caffeine. A 2-month open label clinical trial was initiated with 30 patients who used an oral mixture (Healthy CurbTM) of amaylase inhibitor (500 mg white kidney bean extract) plus 500 mg of NTFactor™ 30 min before each meal. Weight and measurements were taken weekly, appetite was assessed4 and fatigue was determined using the Piper Fatigue Scale. 5 Sixty-three percent of the participants lost an average of 6 pounds along with 2.5 and 1.5 inch reductions in waist and hip circumference, respectively, and the entire group of participants lost an average of 3 pounds with average reductions of 1.5 and 1 inch waist and hip circumference, respectively. Participants experienced gradual and consistent weight loss along with waist and hip, body mass index (BMI) and basal metabolic rate (BMR) reductions during the entire trial. There was a 44% reduction in overall hunger with reduced cravings for sweets; therefore, notable appetite suppression occurred. Using the Piper Fatigue Scale the entire test group showed an average of 23% decrease in overall fatigue. Blood lipid profiles generally improved, suggesting improved cardiovascular health, and no adverse effects were noted clinically or found in blood chemistries.

Conclusions: The vast majority of the subjects in this trial lost weight, showed decreased waist and hip measurements and overall body mass. Their overall



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fatigue was reduced, and they experienced marked appetite suppression. The product was completely safe and void of any side effects and was extremely well tolerated. HealthyCurb appears to be a safe and effective means for CFS patients to manage weight without changes in eating or exercise patterns.

INTRODUCTION

Being overweight or obese can present health issues and may also lead to serious chronic illnesses. Dieting is difficult because dieters are unable to endure the commitment required to achieve their weight loss goals. One of the most common complaints of dieters is the constant feeling of hunger associated with reducing calorie intake. Another complaint dieters experience is the lack of energy due to decreased caloric consumption. Nutritional Therapeutic, Inc. has developed a safe, allnatural food-based supplement (Healthy CurbTM) that has been reported to reduce appetite, increase energy levels, reduce fatigue, block starch uptake and help with weight management. The supplement contains NTFactor™, which has been shown to reduce fatigue and repair mitochondrial membranes.^{2,3} This study was designed to explore the degree of appetite suppression, the degree of energy level, fatigue reduction, changes in specific blood markers for metabolic health and the amount of weight loss and reduction in waist and hip measurements in a 60 day trial.

PROCEDURES

A two-month open label clinical trial was initiated with 30 patients, ages 18 and older, who used an all-natural oral mixture (Healthy CurbTM, http://www.healthycurb.com) of FDA-approved amaylase inhibitor (2 tablets containing 500 mg white kidney bean extract plus 500 mg of NTFactorTM) 30 min before each meal. All subjects filled out a medical intake form at Tustin Longevity Center. The medical staff determined if participants were qualified to enter the study

based on medical history. Chronic fatigue was an important entry criteria. Weight, waist and hip measurements were taken weekly, appetite was assessed by the procedures of Arumugam et al.,4 and fatigue was determined using the Piper Fatigue Scale.⁵

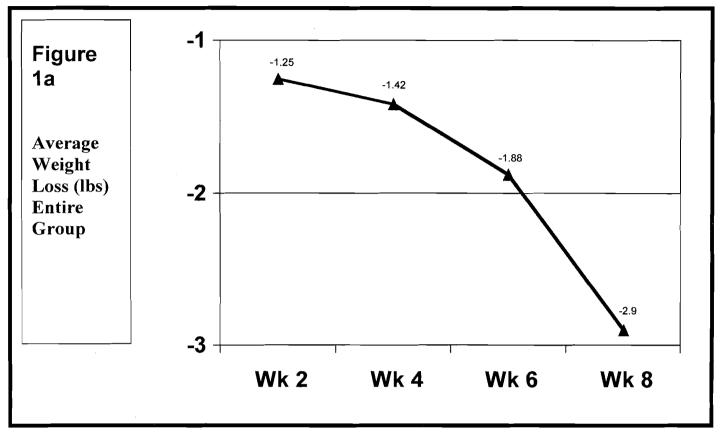
Blood samples were taken at the beginning of the study and at the end of the study. Weight, body composition and measurements were taken every two weeks until the end of the study.

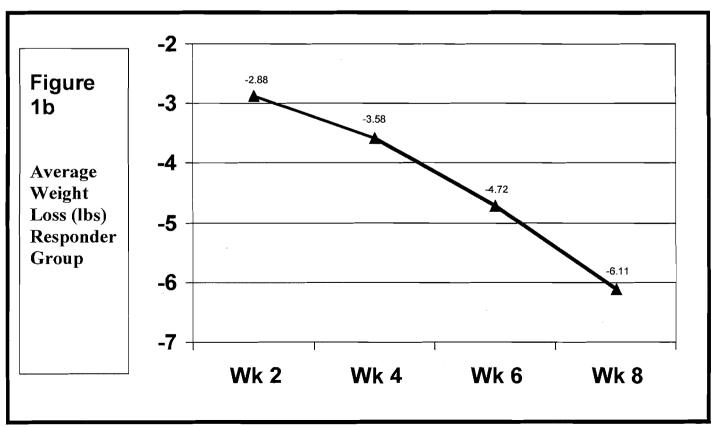
During this two-month study the NIH guidelines for alcohol consumption were followed: "Moderate drinking is one drink a day for women or anyone over 65, and two drinks a day for men under 65."

RESULTS

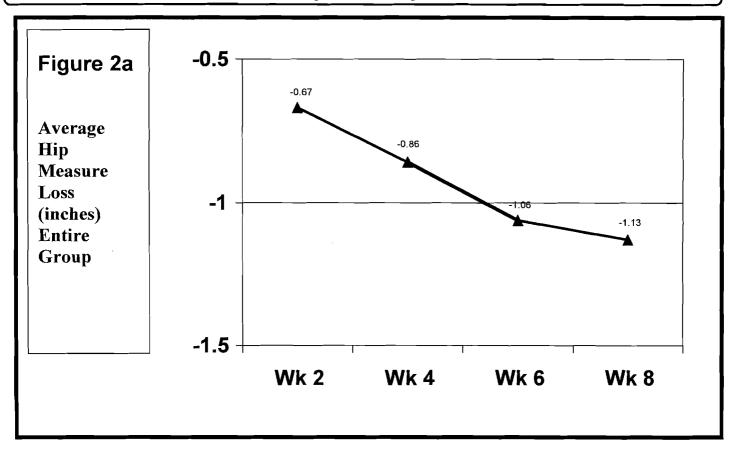
Weight and Girth Reduction: The entire group of participants lost an average of 3 pounds (Fig. 1a) with average reductions of 1.5 and 1 inches in hip and waist circumference, respectively (Figs. 2a, 3a). Sixty-three percent of the participants (responder group) lost an average of 6 pounds (Fig. 1b) along with 2.5 and 1.5 inches reduction in hip and waist circumference, respectively (Figs. 2b, 3b), and participants experienced gradual and consistent weight loss along with waist and hip reductions during the entire trial.

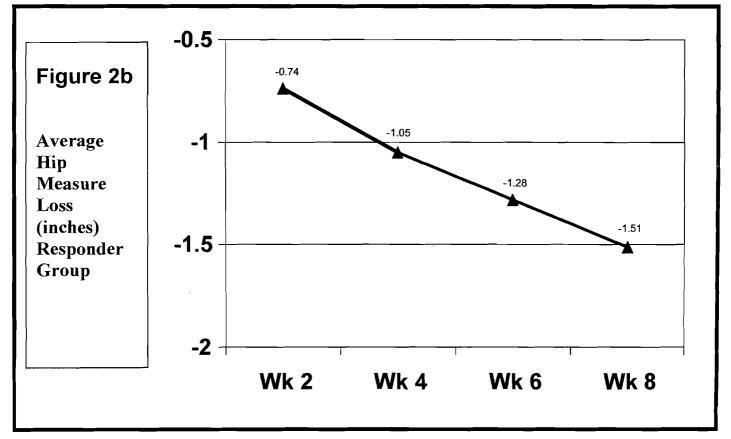
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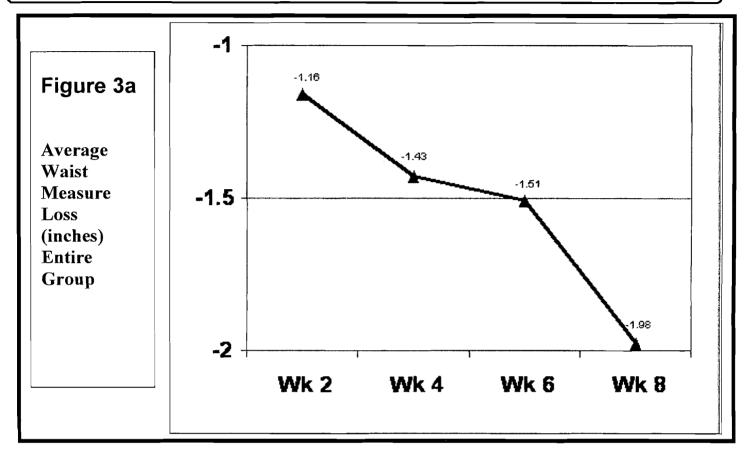


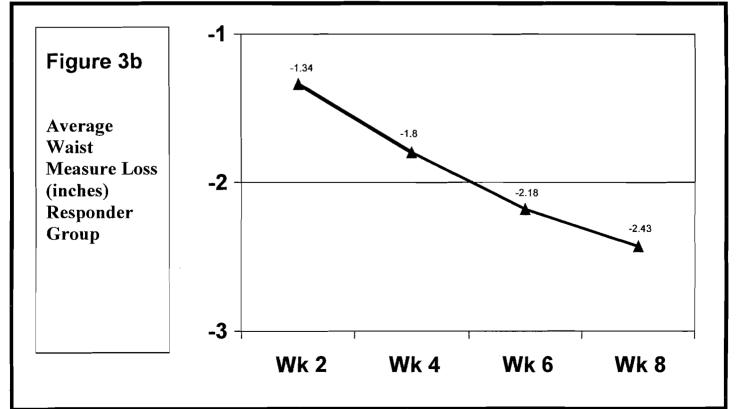
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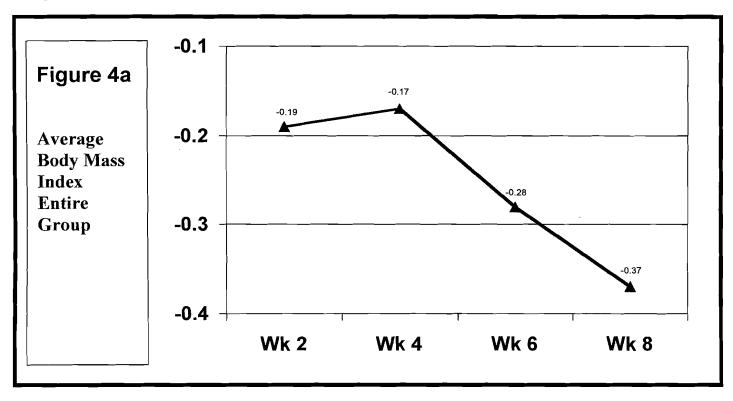
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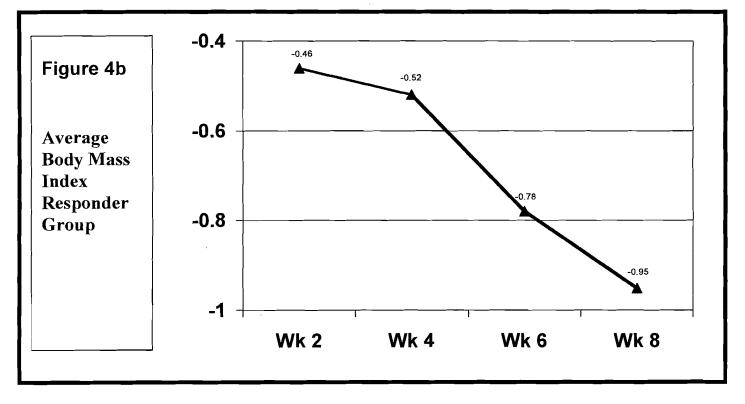




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Body Mass Index Reduction: Body mass index (BMI) was calculated as the weight (in pounds) times 703 divided by height (inches) squared. There was a reduction in average BMI in the entire group of 0.18 (Fig. 4a) and in the responder group of 0.49 (Fig. 4b).

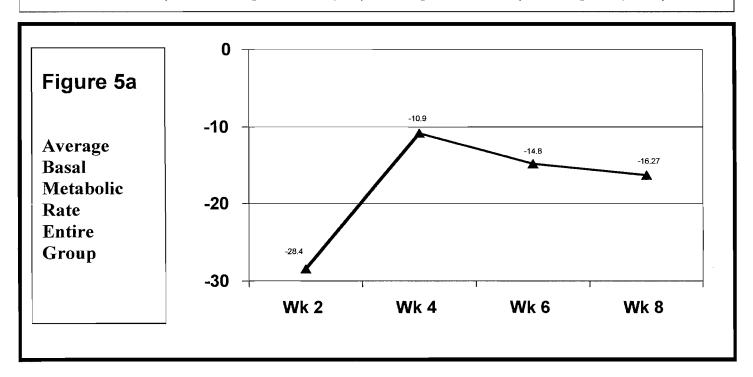


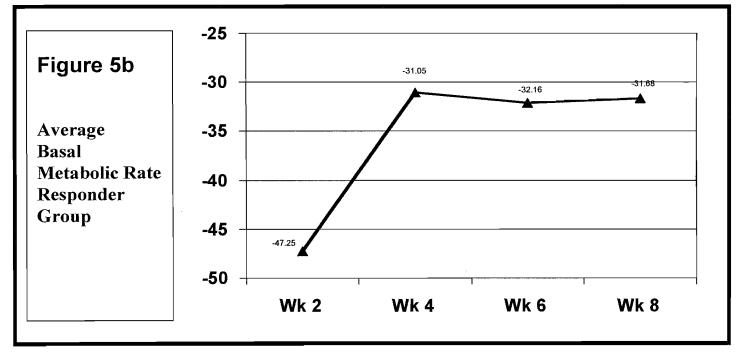


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Basal Metabolic Rate Reduction: Basal Metabolic Rate (BMR) uses the variables of height, weight, age and gender to calculate a rate of resting metabolism. The overall change in BMR and change in the responder group are shown in Figs. 5a, 5b. These were calculated as follows:

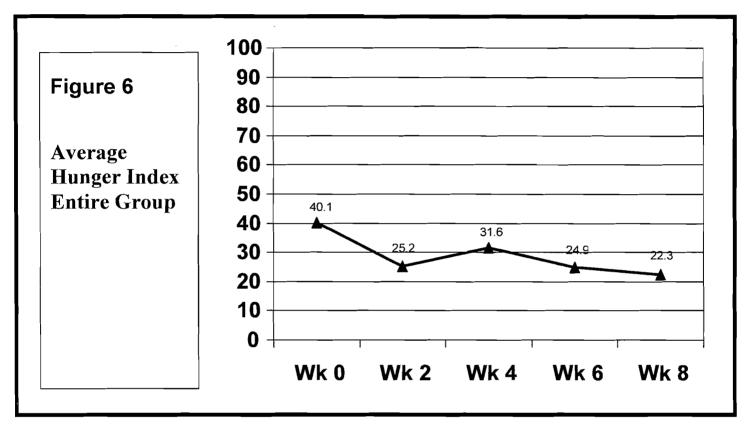
Women: BMR = $655 + (9.6 \times \text{weight in kilos}) + (1.8 \times \text{height in cm}) - (4.7 \times \text{age})$ **Men**: BMR = $66 + (13.7 \times \text{weight in kilos}) + (5 \times \text{height in cm}) - (6.8 \times \text{age in years})$





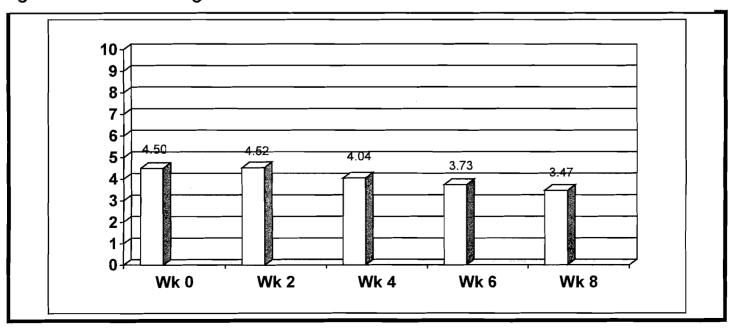
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Appetite Suppression: There was a 44% reduction in overall hunger (Fig. 6) with reduced cravings for sweets; therefore, notable appetite suppression occurred.



Fatigue Suppression: Using the Piper Fatigue Scale the entire test group showed an average of 23% decrease in overall fatigue during the trial (Fig. 7)

Figure 7. Overall Fatigue Scores



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Blood Lipid Profiles: Blood lipid profiles generally improved (Table 1), suggesting improved cardiovascular health, and no adverse effects were noted clinically or found in blood chemistries (data not shown).

Table 1. Blood Lipid Chemistry

Measurement	Day 0	Day 60
Glucose	104.8 mg/dl	104.4 mg/dl
Cholestrol	209.6 mg/dl	200.7 mg/dl
Triglycerides	142.6 mg/dl	129.2 mg/dl
HDL	56.9 mg/dl	58.0 mg/dl
LDL (Calc)	124.2 mg/dl	116.8 mg/dl
VLDL (Calc)	28.5 mg/dl	25.8 mg/dl
Cholesterol/HDL Ratio	3.9	3.7
LDL/HDL Ratio	2.4	2.1

DISCUSSION

Healthy Curb™ has proven to be a safe, all natural food-based supplement that allows weight control without the use of stimulants or herbs that could cause side effects. During the brief trial no adverse effects were reported, and blood chemistries and lipid analyses indicated that subjects actually had improved lipid profiles at the end of the trial.

A common complaint while taking dietary

supplements is the loss of energy and stamina. Healthy CurbTM contains NTFactorTM, a supplement known to naturally decrease fatigue and increase energy. 1-3 During the trial subjects reported increased energy and decreased fatigue, and this was shown by reduction in Piper Fatigue Scores. Thus a major problem in all natural weight loss products was overcome by including NTFactorTM. They also had reduced hunger and reduced cravings for sweets.

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DIETARY SUPPLEMENT HEALTHY CURB FOR REDUCING WEIGHT, GIRTH, BODY MASS, APPETITE AND FATIGUE WHILE IMPROVING BLOOD LIPID VALUES WITH NTFactor LIPID REPLACEMENT THERAPY

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Participants experienced gradual and consistent weight loss along with waist and hip, body mass index (BMI) and basal metabolic rate (BMR) reductions during the trial. Thus Healthy CurbTM proved to be a safe and effective weight loss supplement.

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