A weight management program, including a blend of natural compounds, facilitates weight loss in overweight men and women: a pilot study

Steven M Wood, PhD, RD; Stephen Poole, BS; Doug Burke, PhD; Mark Bartlett, PhD; Angela Mastaloudis, PhD. Center for Anti-Aging Research, Nu Skin Enterprises, Provo, UT

ABSTRACT #851.14

Increased rates of overweight globally highlight the need for effective weight management tools. Unfortunately, the complexity of weight management creates challenges and successful interventions backed by well-controlled studies are lacking. The purpose of this study was to test a blend of natural compounds along with a diet and exercise program for the ability to support healthy weight loss in humans. Sixty-nine subjects (47 Women (W) and 22 Men (M)) average age 43.9 ± 9.8 years and an average Body Mass Index (BMI) of 30.6 ± 3.4 were instructed to follow the diet, exercise and supplement program for 2 weeks. 91% of subjects lost weight, average weight loss after two weeks was -3.8 ± 3.1 lbs (-3.0 ± 2.9 lbs W; -5.4 ± 3.0 lbs M) and average fat loss of -1.4 ± 2.3% (-1.3 ± 2.4% W; -1.6 ± 1.9% M)(all changes $p < 0.05$). Although men lost more weight than women, women experienced greater changes in body measurements. Women exhibited statistically significant reductions in waist, hip, arm and ankle circumferences while no changes were recorded in men. No adverse events were reported and laboratory values were within normal limits. A weight management program made up of a unique blend of natural compounds, a diet and an exercise regime, led to successful reductions in body weight and % body fat within 2 weeks. These positive findings warrant further investigation including a longer term intervention and a randomized placebo controlled trial.
Research was supported by Nu Skin Enterprises, Provo, Utah

INTRODUCTION

Excessive body weight is becoming a concern around the world, for example, over half of the American adult population is overweight or obese. Being overweight is associated with several conditions or chronic diseases: hypertension, elevated cholesterol, type 2 diabetes, stroke, osteoarthritis, and sleep apnea. Economically, the annual costs for excessive body weight on medical expenses and lost income is approximately 70 billion dollars, in the United States.

There are many factors that affect body weight or influence a person's ability to lose weight. We have identified several natural ingredients that can assist with the body's ability to burn fat as well as maintain lean body mass (muscle). Furthermore, it is not practical for setting a specific energy dietary level for every body shape and size.

Many diet programs focus solely on energy (kcals) intake yet the body responds differently to macronutrients i.e. with simply carbohydrates, the insulin response triggers the body to store fat. Furthermore as dietary energy levels decrease, the body meets its demands through utilizing protein and lean body tissue. As a person loses weight there can be a significant loss of muscle which can adversely affect body weight maintenance . Therefore a goal for weight maintenance should be preservation of lean tissue and utilization of fat stores. With this in mind, dietary protein provides an essential branched chain amino acid, leucine to signal and regulate several processes in the muscle. Interestingly, the majority of dietary protein is consumed primarily at the evening meal which means that throughout the day the body does not have adequate levels of leucine. Furthermore, the typical American consumes mainly carbohydrates for breakfast and lunch signaling the body to store fat.

We designed a weight management plan consisting of a diet plan where protein (approximately 30 grams) is consumed at each meal. The diet is customized to body size using the fist size for proportions of protein foods, fruits, vegetables, and grains. We have also included dietary supplements that contain ingredients that assist the body to utilize fat to meet energy demands, maintain muscle, and improve sense of wellbeing and motivation. Many of these ingredients were identified by gene expression from rodent studies examining their profile in muscle, adipose, and brain tissues.

The purpose of this study was to understand the effects of natural compounds along with a diet program to determine extent of body composition changes and safety through laboratory values in subjects participating in a 3 month study. The results of this study will provide insights to assist in designing and executing a larger, prospective, double-blind, controlled study.

DESIGN, SUBJECTS, AND METHODS

- Open-label, 90 day study of healthy Women (n=47) and Men (n=22) aged 25 to 65 years of age (BMI 25-40 kg/m^2)
  - Measurements at Baseline, 14 days, 30 days, 60 days, 90 days (only day 14 and 90 shown)
  - Body compositional measurements)
    - ✓ Bod Pod, waist, hip, arm, and ankle, circumference measurements
  - Resting Metabolic Rate (Quark CPET)
  - Questionnaire's and daily diaries
    - ✓ Compliance
  - Pedometer to determine amount of movement
  - Safety
    - ✓ Lab values (comprehensive metabolic profile, complete blood count and differential)
    - ✓ Monitor adverse events
- Study approved by Human Use Committee and in accordance with good clinical practices (GCP)
- All products produced in accordance with good manufacturing practices (GMPs)
- Study listed on Clinicaltrials.gov #NCT01725958

WEIGHT MANAGEMENT COMPONENTS

Days 1-15
Jumpstart

Days 1-90

Fit Supplement	Control Supplement	Protein Shake

Learning Phase

Be Active	Eating Plan

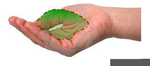
Eating Plan (based on hand size)

6 protein portions- Approximately 30 g protein/meal (2.5 g luecine)

2 Fruit

2 Vegetables

2 Grains



SUPPLEMENT INGREDIENTS

Jump Start powder, *that is mixed in 8 to 16 oz water or favorite beverage*
- Opuntia ficus-indica (Prickly Pear Cactus) Fruit Powder
- Blood Orange extract
- Crocus Sativa extract
- Pomegranate extract

Fit Supplement (1 capsule before each meal)
- Brown seaweed extract containing standardized fucoxanthin
- Green tea extract
- Onion extract containing standardized quercetin
- Blood orange extract
- Cayenne powder

Control Supplement (2 capsules in morning and night)
- Theanine
- Cocoa powder
- Tart cherry powder
- Pomegranate Extract

RESULTS

Table 1. Subject numbers and characteristics

	Subjects (n) Enrolled and completed 14 days	Subjects (n) Completed 90 days	Age (years)**	Baseline BMI**
Females	47	45*	44.1 ± 1.4	31.1 ± 0.5
Males	22	21*	43.2 ± 1.3	31.2± 0.8
Total	69	66	43.8 ± 1.2	31.1± 0.5

*3 Subject withdrew consent (2) or lost to follow up (1)
**Means ± standard error of the mean (SEM)

Table 3. Changes in body circumference measurements.

	Change in Waist Circumference (inches) Day 0-90*	Change in Hip Circumference (inches) Day 0-90*	Change in Arm Circumference (inches) Day 0-90*	Changes in Ankle Circumference (inches) Day 0-90*
Females	-2.9 ± 0.4	-2.5 ± 0.3	-0.9 ± 0.1	-0.6 ± 0.1
Males	-3.1 ± 0.5	-2.3 ± 0.5	-0.8 ± 0.2	-0.4 ± 0.1
Total	-2.9 ± 0.3	-2.4 ± 0.3	-0.9 ± 0.1	-0.5 ± 0.1

*Means ± standard error of the mean (SEM)

Table 2. Body composition changes from baseline to day 14 and 90 (*Means ± SEM)

	Change in BMI Day 0-14	Change in BMI Day 0-90	Change in Body Fat (lbs) Day 0-14	Change in Body Fat (lbs) Day 1-90	Change in % Body Fat Day 0-14	Change in % Body Fat Day 0-90	Change in Fat Free Mass (lbs) Day 0-14	Change in Fat Free Mass (lbs) Day 0-90	Change in Body Weight (lbs) Day 0-14	Change in Body Weight (lbs) Day 0-90	Change in Resting Metabolic Rate (Kcals) Day 0-14	Change in Resting Metabolic Rate (Kcals) Day 0-90
Females	-0.5 ± 0.1	-1.1± 0.2	-3.2 ± 0.7	-12.9 ± 1.9	-1.3 %	-6.0 %	+0.6 ± 0.7	+6.6 ± 1.0	-3.4 ± 0.4	-6.4 ± 1.3	-24.6 ± 32.5	+165.3 ± 39.1
Males	-0.8 ± 0.1	-1.8 ± 0.3	-4.4 ± 0.9	-19.7 ± 2.0	-1.6 %	-8.5 %	-0.5 ± 0.8	+7.5 ± 0.9	-5.4 ± 0.7	-12.1 ± 2.2	+13.8 ± 51.6	+181.4 ± 81.1
Total	-0.6 ± 0.1	-1.3 ± 0.2	-3.7 ± 0.6	-15.1 ± 1.2	-1.4 %	-6.8 %	+0.2 ± 0.5	+7.0 ± 0.7	-3.8 ± 0.4	-8.2 ± 1.2	-10.5 ± 27.5	+179.8 ± 37.8

SUMMARY/ CONCLUSIONS

1. This novel weight loss system was well accepted by participants
2. Weight loss system and products were well tolerated and safe
3. Eighty percent of participants lost weight (Females, n=32 and Males, n=21) while the others maintained or gained weight (Females, n=13 and Males, n=0)
4. Weight loss was primarily from fat mass, maintained fat free mass (muscle)
5. Larger study should be conducted and compared to a typical weight loss program
6. Prospective, randomized, blinded studies should be conducted to examine the impact of supplements and diet eating plan