

**Results for:**

**Prospective, Randomized, Placebo-Controlled, Double-Blinded  
Pilot Clinical Trial for Appetite Suppression  
A Study to Assess the Efficacy and Short-Term Safety of  
RightSize Health & Nutrition Corporation's Proprietary Blend (Appemine)**

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**Design:**

- Prospective, randomized, placebo-controlled, double-blind clinical trial
- The control and placebo groups received diet counseling and participated in a light-to-moderate exercise program
- The duration for the trial was six weeks for both groups
- Equal number of subjects were randomized for both the active and placebo groups
- The research nurses were blinded to the randomization

**Propriety Blend (including dosage and timing):**

- Two doses per day: (two tablets per dose)
- The first dose taken in mid-morning
- Second dose taken in mid-afternoon
- Not taken with food

**Inclusion Criteria:**

- Subjects wishing to learn to manage their weight; subjects who answer an advertisement announcing this trial
- Age Range: 18-70
- Subjects who passed a compliance screening test
- Subjects who passed a health screen
- Subjects able to tolerate the active product or placebo
- Subjects who signed an Institutional Review Board (IRB)-approved consent form

**Exclusion Criteria:**

- Subjects who were non-compliant with testing and taking treatment regimens
- Subjects who were unable to tolerate the treatment blend or placebo
- Subjects under 18 or over the age of 70
- Subjects with moderately severe co-morbid disease, that includes cardiac, pulmonary, renal, hepatic, or active cancer (this determination is subject to the study nurse and/or physician)
- Subjects with insulin-dependent diabetes
- Subjects on medications or other herbal preparations for the treatment of target condition
- Subjects with alcohol abuse as determined by provider interviews or medical history

**Confounding Factors:**

- Age
- Prior attempts at weight management
- Baseline weight or Body Mass Index (BMI)

**Primary Outcomes:**

- Appetite suppression
- Satiety
- Weight loss/gain
- Body composition measures

**Secondary Outcome:**

- Blood pressure
- Overall well-being

**Diet Component:**

The essence of the diet included a very-low amount of refined carbohydrates although the overall plan included equal amounts of total carbohydrates, fats, and proteins. This is not a calorie-restricted diet. The recommended use of carbohydrates involved the use of complex carbohydrates, mostly green vegetables and grains, such as brown rice. We repeatedly emphasized extremely small amounts of refined carbohydrates, including soda, products containing sugar, wheat products, breads, pasta, potatoes, and similar foods.

Each subject will be counseled about these diet concepts at two separate times prior to the initiation of the trial and again at the two and four-week follow-up check-in periods. Subjects were expected to complete food logs several times during the study. The research nurse reviewed these logs with each subject and continued to emphasize the low-refined carbohydrate diets with the subjects.

The use of a non-calorie-restricted diet provides relief for generalizing the study results. The chief restriction for claims and disclaimers involves the use of mentioning that a low-refined carbohydrate diet was followed.

**Exercise Program:**

Subjects were required to comply with a weekly exercise program that included:

- 3 times per week for 20 minutes light-to-moderate aerobic exercises (brisk walking, treadmill, biking, and related exercises)
- 2 times per week for 10 minutes resistance training (weight training, rowing)

Subjects have several options for this work:

- Workout on their own, using a log to record their progress
- Workout at a local gym, using a log to record their progress
- Light equipment at the Clinic

We tailored these programs to appeal to a wide range of individuals while still meeting the exercise requirements. Compliance was assessed by interviews and by reviewing the subject logs.

**Protocol:**

Subjects were recruited from the general population surrounding Bangor, Maine. They met the inclusionary and exclusionary criteria and passed a health-screening test. Subjects' were dropped during the study if they repeatedly failed the compliance standards involving dosing, diet, or exercise.

Subjects were required to sign a Fox Commercial IRB approved informed consent, indicating that they understood all aspects of this trial.

The Study Coordinator instructed all subjects as to the protocol and other details of the study. Subjects will be instructed precisely how and when to take the dietary supplements during the course of this study and how to report adverse reactions and any other pertinent information.

Subjects were randomized into either the placebo or active treatment group. The duration of the study was six weeks. All subjects randomized to receive the placebo were given a six-week supply of the active material for their own use.

Subjects were initially interviewed by phone and subsequently screened into the study by a research nurse at the Herbal Research Clinic at 268 State Street. They were read and then signed a consent form and received a thorough health screen before randomization. They received instructions on how and when to complete the survey instruments and be given a two-week of product or placebo.

They were required to come back to the clinic every two weeks to have their blood pressure, weight, body composition checked and completed a survey and then received an additional two-week supply. This procedure will be repeated at the four and six-week mark.

Any adverse events were reported to RightSize Health & Nutrition and to the Fox commercial IRB using appropriate reporting format.

**Green Tea Blend:**

Green Tea Leaf Extract	100 mg/tablet
Cinnamon Stem	
Galangal Rhizome	
Standardized to 5% total biogenic amines	

100 mgs / tablet  
2 tablets / 1 dose



## Categorical Analysis

- One-to-two point differences have been classified as “some improvement”, while three-to-four point differences as “significant”, and five or more point improvements as “dramatic”.
  - No Improvement
  - Any Improvement: One point or greater
  - Some Improvement: Specifically one-to-two point improvement
  - Significant Improvement: Specifically three-to-four point improvement
  - Dramatic Improvement: Specifically five-or-more point improvement
- All categories were analyzed using the Chi-Square test. Some analyses used Fisher’s Exact Two-Tail t-test, due to the small cell limitations. Fisher’s is another type of chi-square test that must be utilized during scenarios of small cell sizes. **Note:** the definition of small cell sizes refers to comparing small number of subjects for a statistical test. For example: even though thirty-one subjects completed the product phase, when we compare the numbers who rated a “dramatic” improvement for a specific end-point, there may have been only four (4) subjects in the treatment group and none from the placebo group. This comparison involving four and none triggers the small-cell definition.
- These category improvements were determined *a priori* by the medical advisory group

## Statistical Significance

These criteria were set prior to the analysis.

Highly Significant:                       $p < 0.05$

Significant:                               $p < 0.10$

Statistical Trend:                       $p < 0.15$

## Randomized, Placebo-Controlled Clinical Trial Results

### Subject Numbers

Twenty-six (26) subjects were randomized for this trial (thirteen (13) in each group). Eight (8) subjects completed the product phase of this trial while seven (7) individuals completed the placebo phase of this trial.

There were no statistical differences between the groups with respect to clinically important baseline and demographic parameters. This included age, baseline weight, body mass index (bmi), behavioral variables (smoking, alcohol, caffeine, and the like),

and the co-morbid risk profile (diabetes, heart disease, pulmonary conditions and the like). This data provides evidence that the randomization worked properly and that potential selection biases were avoided.

**Appetite Suppression:**

“When hungry, how much control do you have over your appetite?”

	<b>Placebo</b>	<b>Product</b>
<b>Mean Improvement</b>	0.71	2.57
<b>Any Improvement</b>	42.9%	57.1%
<b>Some Improvement</b>	28.6%	0%
<b>Significant Improvement</b>	14.3%	57.1%
<b>Dramatic Improvement</b>	0	14.3%

“How has your appetite changed since using this product?”

	<b>Placebo</b>	<b>Product</b>
<b>Mean Improvement</b>	0.57	2.25
<b>Any Improvement</b>	28.6%	75%
<b>Some Improvement</b>	28.6%	25%
<b>Significant Improvement</b>	0	37.5%
<b>Dramatic Improvement</b>	0	12.5%

**Weight Loss: (numbers represent average weight loss)**

	2-Week	4-Week	6-Week
Placebo	1.75	2.25	3.01
Product	1.83	2.51	4.27

This means that the entire group of placebo subjects lost 1.75 pounds at the two-week mark, whereas those on product lost 1.83 pounds.

**Conclusions:**

This product produced only marginal weight loss with respect to the placebo group, but demonstrated a marked improvement in appetite control in a variety of questions. The appetite control translated to a weight loss per week of 0.71 pounds per week, or 0.21 pounds per week over the placebo group.

The average improvement in overall appetite control was 2.25 points per subject, compared to an improvement of 0.71 for the placebo group. The trial was too small to detect a statistical difference, but with a larger trial, this difference would be significant.