Global Clinicals, Inc.

FINAL REPORT

PREPARED FOR: ADDY PRODUCTS, LLC
6815 East Camelback,
SCOTTSDALE, AZ 85251
TEL: (602) 326-7730
ATTN: TOM VELLA, OWNER

TITLE: CLINICAL EVALUATION OF THE EFFECTS OF ADDY™ DIETARY SUPPLEMENT PREPARATION ON WEIGHT IN OVERWEIGHT & OBESE SUBJECTS

PROTOCOL #: 4695-6-0714

DATE: SEPTEMBER 2015

CONFIDENTIAL

STUDY INFORMATION

Financial Support:	**ADDY PRODUCTS, LLC** 6815 East Camelback Scottsdale AZ 85251 Tel: (602) 326-7730
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PROTOCOL SYNOPSIS

Study Sponsor:	ADDY PRODUCTS, LLC 1725 W. Williams Dr., Bldg F, Ste. 66, Scottsdale, AZ 85027
Contract Research Organization (CRO):	GLOBAL CLINICALS, INC. 6520 Platt Avenue, #305, West Hill, CA, 91307 www.GlobalClinicals.com
Study Title:	Clinical Evaluation of the Effects of ADDY™ Dietary Supplement Preparation on Body Weight in Overweight & Obese Subjects
Protocol Number:	4695-6-0714
Name of Products:	ADDY™ Dietary supplement
Test Products, Route and Duration:	The test products were administered orally 30 minutes prior to a major meal (breakfast or lunch, or dinner), twice daily, for 12 week (6 capsules total per day)
Design:	Twelve week randomized double blind placebo controlled prospective clinical study, single site
Number of Subjects:	N=74 (n=37 per group, 2 groups)
Objectives and Endpoints:	• The primary objective of this study was to assess the effectiveness and tolerability of ADDY™ dietary supplement weight loss formulation along with diet and exercise, in reducing body weight and hunger, and increasing satiety, mood and energy, when compared to placebo and diet and exercise alone. • To evaluate safety via monitoring, exam, side effects
Questionnaires:	• Subjects Side Effects Form • VAS questionnaires for Hunger, Satiety, Mood and Energy • Global Evaluation (End of Study)
Study Related Activities:	• Blood collection for Complete Metabolic Panel • Collect data / online patient login /data entry • All data collected property of the Sponsor
Subject Population:	Adults (18 – 65 years of age) who meet Study Protocol Inclusion/Exclusion criteria. Male and female, in good general health
Method of Subject Assignment:	Telephone prescreen prior to scheduling site visit and MD exam. Randomized enrollment into one of two groups Signed Informed Consent, Bill of Rights, and Medical History
Inclusion Criteria:	To be eligible for this study, subjects must meet all of the following criteria. Subjects must: (additional details per Study Protocol) • Male & female volunteers • Ages between 18 and 65 years

	• In general good health • BMI= 27-37 • Agree to exercise for 30 minutes of walking 4 times a week • Agree to diet maintenance per RD evaluation • Sign and date the Informed Consent Form
Exclusion Criteria:	Subjects will be excluded if they meet any of the exclusion criteria, as per the Study Protocol
Study Duration:	Twelve weeks
Site/Study Visits:	Three visits – (Screen/Baseline, Week 6 and 12)
Data Collection to Sponsor:	• Statistical analyses • Graphs and tables • Regulatory paperwork (IRB) • CRFs • Final Report
Statistical Methods:	• Independent T-test • Wilcoxon Rank Sum, Chi-Square and Fisher's Exact tests
Compliance:	• Telephone contact • Product administration • Site visits • Monitoring
Data Collection:	Site visit, telephone screen and follow up, online input, product admin log, lab results, stats, CRFs, etc.
Subject Compensation:	Up to $225.00 USD each

1. EXECUTIVE SUMMARY

1.1 BACKGROUND

Obesity represents not only a risk to the individual obese patient but also a challenge to an already strained health care system. As a result many novel pharmacological and surgical means are being deployed in the war against fat, including dietary supplement preparations. One such preparation, ADDY™ is the subject of this study.

1.2 PURPOSE

The primary purpose of this 12 week randomized double blind placebo controlled prospective clinical study was to assess the efficacy, safety and tolerability of ADDY™ dietary supplement weight loss formulation, along with diet and exercise, in reducing body weight and hunger and increasing satiety, mood and energy, when compared to placebo and diet and exercise alone.

1.3 DESIGN

This was 12 week randomized double blind placebo controlled prospective clinical study.

1.4 RESULTS & DISCUSSION

There were no significant differences between groups in any of the weight, anthropometric or body composition parameters, or energy and mood scores. There were, however, significant differences in favor of the active group for hunger and satiety assessments at 6 and 12 weeks. These results are encouraging and may indicate that either a longer exposure to this supplement preparation or higher doses, or both, will translate into changes in body weight and energy and mood, as well. Future studies should consider these options. The study preparation was well tolerated and there were no significant differences between active and control groups across side effects or in their total number.

2. INTRODUCTION

The Center for Disease Control (CDC), defines obesity as an excess amount of adipose tissue in relation to lean body mass (1). According to the National Health and Nutrition Examination Survey (NHANES), 61% of the U.S. population is either overweight or obese (1). NHANES II and NHANES 1999 data indicate that the prevalence of overweight people in the U.S. (20 -74 years) was 35% in 1999 and that for obese 27%, almost twice the 15% number in 1980. Those who are obese are more likely to experience kidney trouble, diabetes, high blood pressure, heart disease, pregnancy complications, psychological problems, sudden death, obstructive sleep apnea, Pickwickian Syndrome, congestive heart failure, limited daily activities, and liver damage (2- 4).

These facts taken together indicate that obesity represents not only a risk to the individual obese patient but also a challenge to an already strained health care system. As a result many novel pharmacological and surgical means are being deployed in the war against fat, including dietary supplement preparations. One such preparation, ADDY™ is the subject of this study. It was hypothesized that the combination of ingredients in this formulation will synergize to reduce hunger, maintain satiety and increase energy expenditure, thereby leading to weight loss.

The primary purpose of this 12 week randomized double blind placebo controlled prospective clinical study was to assess the efficacy, safety and tolerability of ADDY™ dietary supplement formulation for weight loss, along with diet and exercise, in reducing body weight and hunger, and increasing satiety, mood and energy, when compared to placebo and diet and exercise alone.

3. MATERIALS AND METHODS

3.1 SUBJECTS AND STUDY DESIGN

The primary purpose of this 12 week randomized double blind placebo controlled prospective clinical study was to assess the efficacy, safety and tolerability of ADDY™ dietary supplement weight loss formulation, along with diet and exercise, in reducing body weight and hunger, and increasing satiety, mood and energy, when compared to placebo and diet and exercise alone. Efficacy was assessed by measuring body weight, impedance, anthropometrics and satiety, and safety by measuring resting heart rate, blood pressure, and monitoring side effects through subjective questionnaires.

Consenting eligible male and female subjects, meeting the inclusion/exclusion criteria, were required to visit the study site three times for screening, Week 6 and week 12 activities. There were a total of seventy four subjects enrolled, randomly assigned to two groups of thirty eight subjects each, corresponding to placebo and active. Study medication was provided as indicated below under “product use”.

During the screening visit to the study site, Informed Consent and Bill of Rights forms were signed by subjects after a thorough review with the PI or CRC. Subjects must have been able to read, understand, accept, and sign the Informed Consent form. Subjects completed a screening health questionnaire and underwent a brief physical examination by the PI. A urine pregnancy test was carried out for female patients just prior to the start of the study.

Subjects selected to participate in the study were provided with instructions on completing the various forms related to the study endpoints and study procedures, and were instructed to check with the Investigators or Clinical Research Coordinator (CRC) if they had any questions.

All groups were asked to exercise four times a week by walking briskly for 30 minutes, while being able to carry out a conversation or periodically recite a text of their choice. Subjects were also asked to record their exercise dates and time via diary for each walk.

Subjects provided a 3-day log of meals and snacks, which they brought to the site on the initial visit date. A registered dietician (RD) evaluated subject diets based on these logs and provided appropriate recommendations for food to eat during the study in the form of possible menus. These data were used only for informational purposes.

Side effects were monitored using a questionnaire, vitals and EKG. Study activities are shown in **Table 1- Study Schedule of Events**.

3.1.1 STUDY ENDPOINTS

The following endpoints were evaluated at various intervals as indicated below (also see **Table 1- Study Schedule of Events**):

Efficacy Measurements

- BMI measurements (0, 6 and 12 weeks)
- Body weight measurements (0, 6 and 12 weeks)
- Body fat calipers at abdomen and impedance % body fat via BIA scale
- Anthropometrics- height, weight, hip and waist circumference (0, 6 and 12 weeks)
- Satiety VAS scales- (0, 6 and 12 weeks-administered during the study an hour after breakfast, lunch and dinner)
- Energy VAS scales- (0, 6 and 12 weeks-administered an hour after taking the Product)

Safety Measurements

- Subjective side effect questionnaire (6 and 12 Weeks)
- Vitals: HR, BP (0, 6 and 12 weeks)
- Physical exam
- Medical history (screening)
- Comprehensive metabolic panel (6 and 12 weeks)
- Electrocardiogram (EKG) (week 0)

3.1.2 SUBJECTS AND SUBJECT SELECTION CRITERIA

Subjects were recruited from the clinical private practice setting, online ads, local newspaper ads, and word of mouth. Eligibility was assessed through telephone pre-screening. The study protocol and consent form were approved by Sterling IRB, 6300 Powers Ferry Road, Atlanta, Georgia, 30339.

Inclusion Criteria

- Male and female volunteers
- Ages between 18 and 65 years
- In general good health
- BMI = 27-37
- Agree to exercise for 30 minutes by walking 4 times a week
- Agree to diet maintenance per RD evaluation (See study design for details)

- Must be able to read, understand, accept, and sign the informed consent document.

Exclusion Criteria

Subjects who met any of the following conditions or medical history were excluded:

- If they fail the physical exam by the Principal Investigator (PI)
- If they have any metabolic disorder including known electrolyte abnormalities
- If they have heart disease, arrhythmias, diabetes, thyroid disease, or hypogonadism, a history of hypertension, hepatorenal, musculoskeletal, autoimmune, or neurologic disease, or any other condition deemed exclusionary by the PI.
- If they are taking thyroid, hyperlipidemic, hypoglycemic, anti-hypertensive, anti-depressant, or androgenic medications or any other medications deemed exclusionary by the PI
- If they have taken nutritional supplements that may affect muscle mass (e.g., creatine, HMB), fat loss (e.g., ephedra) or anabolic/catabolic hormone levels (androstenedione, DHEA, etc.) within one month prior to the start of the study
- Using any fat loss supplements, special diet program, steroids, and other athletic performance enhancing supplements or drugs.
- If they are currently using any medication that conflict with the product ingredients
- Pregnant or lactating women or women not taking medically approved birth control.
- Women planning to become pregnant within 30 days of the start of the study or during the study period
- Habitual smoking
- More than 2 alcoholic drinks per day average 14 per week

3.1.3 STUDY PRODUCTS

The following was the composition of the test products for all oral formulations and spray:

Active capsule

ADDY™ supplement (per capsule)

a. Active ingredients:

- Caffeine: 15 mg
- Whole Green Coffee Powder: 1159 mg
- Chlorogenic Acid: 42 mg

b. Inactive Ingredients:

- Gelatin,
- Rice Bran
- Chlorophyll

Placebo capsule

a. Active ingredients: None

b. Inactive Ingredients:

- Rice Starch capsules
- Chlorophyll (colorant)

3.1.4 MANUFACTURERS

Active and Placebo were both manufactured and supplied by ADDY Products, LLC, Scottsdale, AZ

3.1.5 PRODUCT ADMINISTRATION

Subjects were instructed to take 3 capsules 30 minutes prior to a major meal (breakfast or lunch, or dinner), twice daily, for 12 weeks. (6 capsules total per day)

3.2 STATISTICAL ANALYSIS

A randomized treatment list was generated for assigning each subject to the active or placebo treatment group. For continuous measures, means and standard deviations were calculated for demographic and vitals measures, and medians and interquartile ranges (IQR) were calculated for hunger, satiety, energy and mood VAS scales. Independent samples t-test were used to compare means between treatment groups and Wilcoxon Rank Sum tests were used to compare medians between treatment groups. Chi-Square and Fisher's Exact tests were used for categorical variables. SAS (SAS Institute, Cary NC) was used for all analyses and the accepted level of significance was α=0.05.

4. RESULTS

4.1 STUDY SUBJECT FLOW

Seventy four subjects were enrolled into the study and randomly assigned into one of two treatment groups, active or placebo, each consisting of thirty eight subjects. **Table 2- Study Subject Flow Chart** summarizes study subject flow information.

4.2 DEMOGRAPHICS, BODY MEASUREMENTS AND VITALS

Demographics, body measurements and vital signs for baseline are reported in **Table 3A- Demographics, Body measurements and Vitals- Baseline**. At baseline screening, no significant differences were found between treatment groups for age, gender and vital signs (systolic and diastolic pressure and pulse). There were also no significant differences between treatment groups for height, weight, BMI, % fat from BIA scale, waist circumference and body fat caliper measurements. Hip circumference was higher in the active group ($p=0.04$).

Body measurements and vital signs for Weeks 6 and 12 and changes from baseline are reported in **Tables 3B and C- Body Measurements and Vitals- Weeks 6 and 12,** respectively.

Between group comparisons: There were no significant differences between treatment groups at the week 6 follow-up. At 12 weeks, active mean body fat caliper was higher than the placebo ($p=0.05$), while the body fat caliper change from baseline was not significant between treatment groups ($p=0.30$).

Within group comparisons: In the active group there was a significant increase in systolic and diastolic blood pressure from baseline at week 6 ($p<0.05$). In the placebo group, mean changes from baseline at week 6 decreased for weight and pulse and increased for % fat from BIA scale ($p<0.05$) and at week 12 increased for systolic and diastolic blood pressure ($p<0.05$).

4.3 HUNGER AND SATIETY VAS SCORES

Table 4A to C- Hunger and Satiety VAS Scores, for Baseline and weeks 6 and 12 respectively, show these scores and changes from baseline. Changes from baseline are the relevant data here because there were significant differences between groups at baseline. At baseline there were significant treatment differences at time B for hunger Q1-Q3 and for satiety Q4 at times A and B. Times A and B refer to the one time daily

that subjects chose to fill their VAS forms following their supplement dose- at either breakfast or lunch, or dinner[1].

Hunger and Satiety questionnaires are shown in **Appendix 1** and abbreviated wording is included in the tables and results below when the question is first mentioned to be significant.

Between group comparisons: At week 6, changes from baseline at Time A, for hunger Question 2 (Desire to eat) there was a decrease in the active by comparison to the control group ($p<.005$), and trends for a decrease in hunger Question 1 (How hungry), $P< 0.07$ and an increase in hunger Question 3 (How full), $p<0.09$, both at Time B.

At week 12, changes from baseline, (time B) for hunger Questions 1 & 2 scores were lower than the placebo scores ($p=0.01$ and 0.03, respectively). For satiety Questions 2 (How full), Time A, there was an increase, $P=0.02$ (this same question at Time A was also significant for the actual scores on this question, not just change from baseline, $P<0.5$) and Question 3 (How much can eat), time A, there was a decrease, $P<0.05$ by comparison to the control group. For Question 4 (Desire to eat), Time A, there was a trend for decrease, $P<0.06$, by comparison to the control.

Within group comparisons: At week 6 for the active there was a significant decrease from baseline (time B) for hunger Questions 1 and 2 in the active group ($p<0.05$) and a trend increase (Time B) for hunger for Question 3, $p<0.09$.

At week 12 for the active there was a decrease for hunger Question 1 (Times A&B), $p<0.05$, an increase for satiety Question 2 (Time A), $P<0.05$ and a decrease for satiety Questions 3 and 4 (Time A), $P<0.01$

4.4 ENERGY AND MOOD VAS SCORES

Table 5A to C- Energy and Mood VAS Scores, for Baseline and weeks 6 and 12 respectively, show these scores and changes from baseline. At baseline there were no significant treatment differences at Times A or B for any of the questions. Times A and B refer to the one time daily that subjects chose to fill their VAS forms following their supplement dose- at either breakfast or lunch, or dinner (see footnote 1 and "Product Administration" section).

Energy and Mood questionnaires are shown in **Appendix 2** and abbreviated wording is included in the tables.

[1] Subjects were instructed to take 3 capsules 30 minutes prior to a major meal (breakfast or lunch, or dinner), twice daily, for 12 weeks. (6 capsules total per day)

Between group comparisons: There were no significant differences between treatments for any of the questions at any time of the points for either original or change from baseline scores, P<0.05.

Within group comparisons: In the active group at weeks 6 and 12, energy decreased for Q1 time B (p<0.01), Q2 time A & B (p<0.05) and at week 12 for Q4 times A & B (p<0.05). At week 6 the active group mood increased for Q4 time A (p<0.05) and decreased for Q2 time B (P<0.01). In the placebo group at week 6, energy decreased for Q1 time A (p<0.05) and Q2 time A & B (p<0.01) and mood decreased for Q2 time B (p<0.05). At week 12, in the placebo group energy decreased for Q1 time A (p<0.05), Q2 time B (p<0.05) and mood decreased for Q5 time A (p<0.05). These changes, however, occurred for the most part in both the control and active groups and therefore are unlikely to be attributable to the supplement. They are marked by two or three asterisks (*) in **Tables 5A-C**.

4.5 COMPREHENSIVE METABOLIC PANEL

Tables 6A and B- Comprehensive Metabolic Panel summarizes the data for the metabolic panel blood chemistry, which was performed at baseline (**Table 6A**) and week 12 (**Table 6B**). There were no significant differences between groups for any of the parameters at baseline. The placebo group mean sodium level was lower than the active (p=0.01) at week 12. He values for both groups, however, were within the normal ranges for sodium and therefore this difference is not of clinical significance.

4.6 GLOBAL EVALUATION QUESTIONNAIRE

The responses to the five questions for each group are listed in **Table 7- Global Evaluation Questionnaire.** There were no significant differences between groups on any of the questions (p>0.05).

4.7 EXERCISE COMPLIANCE

Table 8- Number of Times Exercised, summarizes the number of times subjects in the two groups exercised per week. There were no significant differences between groups at weeks 6 and 12 or for the total number of times for the entire 12 week length of the study. P<0.5). The information also verifies that subjects complied with the protocol 4 time a week, 30 min walk, requirement for exercise.

4.8 DROPOUTS

There were 15 (40.5%) and 16 (43.2%) dropouts in the active and placebo groups, respectively, **Table 3A- Demographics, Body Measurements and Vitals- Baseline**.

4.9 SUBJECT REPORTED SIDE EFFECTS

Table 9- Subject Reported Side Effects, summarizes the side effects for each group at weeks 6 and 12. There were no significant differences between groups across side effects or in total number of side effects, both at 6 and 12 weeks, (P>0.05).

5. DISCUSSION

There were no significant differences between groups in any of the weight, anthropometric or body composition parameters, or energy and mood scores. There were, however, significant differences in favor of the active group for hunger and satiety assessments at 6 and 12 weeks.

These results are encouraging and may indicate that either a longer exposure to this supplement preparation or higher doses, or both, will translate into changes in body weight and energy and mood, as well. Future studies should consider these options.

The study preparation was well tolerated and there were no significant differences between active and control groups across side effects or in their total number.

6. REFERENCES

1. Defining overweight and obesity. http://www.cdc.gov/nccdphp/dnpa/obesity/defining.htm

2. Andreoli T.E., Bennett, J.C., Carpenter C. C.J., Plum F., Smith Jr., L.H. Eating disorder. In: Cecil Essentials of Medicine, pp 434-438, 3rd Edition. W.B. Saunders Company, Philadelphia, PA

3. Young T. K., Woodmansee B. (2002) Factors that are associated with cesarean delivery in a large private practice: the importance of prepregnancy body mass index and weight gain. Am. J. Obstet. Gynecol. 187(2):312-20.

4. Hofmann K.L., Kupferschmid S., Mussgay L. (2002) Links between body mass index, total body fat, cholesterol, high-density lipoprotein, and insulin sensitivity in patients with obesity related to depression, anger, and anxiety. Int. J. Eat. Disord. (1):58-71.

7. TABLES AND FIGURES

TABLE 1: STUDY SCHEDULE OF EVENTS

Event	Baseline/ Screening/ Week 0	Week 6	Week 12
Informed Consent	Y	N	N
Health History	Y	N	N
Physical Exam	Y	N	N
Bodyweight/BMI, Caliper skin fold mid abdomen, % fat by BIA Impedance	Y	Y	Y
HR and BP	Y	Y	Y
EKG	Y	N	N
Anthropometrics	Y	Y	Y
Hunger & Satiety VAS	Y	Y	Y
Energy VAS	Y	Y	Y
Diet & Exercise Diaries	N	Y	Y
Blood Chemistries	Y	N	Y
Adverse Event Monitoring	N	Y	Y
Site Visits	Y	Y	Y

TABLE 2: STUDY SUBJECT FLOW CHART

ADDY™ Study Protocol # 4695-6-0714	
Date:	8/8/2015
Enrolled:	**74**
Baseline visit	74
Completed Week 6	51
Completed Week 12	43
Drop Outs	31
Screen Failures (DQ/PI)	17
Males	26
Females	48

TABLE 3A: DEMOGRAPHICS, BODY MEASUREMENTS AND VITALS (Baseline)

Variable	Active (n=37)	Placebo (n=37)	p-value*
Gender, n (%) Males Females	 10 (27.0%) 27 (73.0%)	 16 (43.2%) 21 (56.8%)	0.14
Dropouts, n (%)	15 (40.5%)	16 (43.2%)	0.81
EKG – Normal, n (%)	37 (100%)	37 (100%)	---
Age, years mean (SD), range	44.8 (12.5) 18 to 65	43.4 (10.6) 24 to 63	0.60
Baseline	**Mean (SD)**	**Mean (SD)**	
Height, in	65.3 (4.2)	66.0 (3.1)	0.42
Weight, lb.	190.7 (31.0)	190.5 (23.7)	0.97
BMI, kg/m^2	31.4 (3.1)	30.6 (2.6)	0.25
Systolic blood pressure, mmHg	124.0 (12.0)	120.9 (9.1)	0.22
Diastolic blood pressure, mmHg	79.5 (8.0)	78.5 (7.2)	0.57
Pulse, beats/min	76.1 (10.8)	71.8 (10.0)	0.08
BIA scale % fat	38.2 (7.6)	35.3 (7.0)	0.09
Hip circumference, in.	46.9 (3.0)	45.5 (2.9)	0.04
Waist circumference, in.	39.4 (3.8)	39.7 (3.7)	0.77
Body Fat Caliper measurement, mm	39.3 (11.3)	38.8 (10.8)	0.82

*Chi-square and independent samples t-test p-values

TABLE 3B: DEMOGRAPHICS, BODY MEASUREMENTS AND VITALS (Week 6)

Variable	Active (n=37)	Placebo (n=37)	p-value*
Week 6	**Mean (SD)**	**Mean (SD)**	
Weight, lb.	185.5 (28.4)[2]	191.6 (20.5)	0.39
BMI, kg/m^2	31.2 (3.0)	30.6 (2.6)	0.45
Systolic blood pressure, mmHg	127.8 (16.3)	126.4 (12.1)	0.73
Diastolic blood pressure, mmHg	82.6 (8.4)	79.4 (12.1)	0.28
Pulse, beats/min	74.7 (11.6)	69.2 (8.3)	0.06
BIA scale % fat	39.7 (7.1)	37.7 (7.3)	0.33
Hip circumference, in.	46.4 (3.2)	45.3 (4.2)	0.30
Waist circumference, in.	39.2 (4.4)	40.2 (3.7)	0.38
Body Fat Caliper measurement, mm	43.6 (8.9)	40.8 (9.5)	0.30
Week 6 change from baseline	**Mean (SD)**	**Mean (SD)**	
Weight, lb.	-0.8 (3.5)	-2.2 (4.9)**	0.23
BMI, kg/m^2	-0.2 (1.0)	-0.2 (1.1)	0.81
Systolic blood pressure, mmHg	5.2 (11.4)**	5.4 (10.8)**	0.96
Diastolic blood pressure, mmHg	4.8 (6.7)***	1.9 (10.2)	0.24
Pulse, beats/min	0.2 (15.4)	-4.1 (6.8)***	0.21
BIA scale % fat	0.3 (3.0)	2.1 (4.4)**	0.10
Hip circumference, in.	-0.4 (1.1)	-0.6 (3.5)	0.82
Waist circumference, in.	-0.0 (2.4)	0.3 (2.2)	0.64
Body Fat Caliper measurement, mm	3.8 (14.2)	1.7 (13.4)	0.60

*Independent samples t-test p-values between group comparisons
**Paired t-test p-value, p<0.05, within group comparisons
*** Paired t-test p-value, p<0.01, within group comparisons

TABLE 3C: DEMOGRAPHICS, BODY MEASUREMENTS AND VITALS (Week 12)

Variable	Active (n=22)	Placebo (n=21)	p-value*
Week 12	**Mean (SD)**	**Mean (SD)**	
Weight, lb.	186.6 (28.9)[2]	190.8 (22.5)	0.60
BMI, kg/m^2	31.1 (3.2)	30.2 (2.5)	0.31
Systolic blood pressure, mmHg	126.8 (15.3)	126.6 (10.5)	0.97
Diastolic blood pressure, mmHg	79.3 (9.2)	82.6 (9.1)	0.25
Pulse, beats/min	74.1 (10.6)	70.6 (8.7)	0.24
BIA scale % fat	38.4 (9.3)	36.1 (6.5)	0.12
Hip circumference, in.	46.2 (4.2)	46.0 (2.5)	0.80
Waist circumference, in.	39.2 (4.2)	40.0 (3.8)	0.53
Body Fat Caliper measurement, mm	44.2 (7.0)	38.8 (10.3)	0.05
Week 12 change from baseline	**Mean (SD)**	**Mean (SD)**	
Weight, lb.	-0.8 (5.7)	-1.8 (6.8)	0.61
BMI, kg/m^2	-0.1 (1.0)	-0.3 (1.1)	0.61
Systolic blood pressure, mmHg	3.2 (14.0)	4.7 (10.4)**	0.69
Diastolic blood pressure, mmHg	0.9 (11.0)	5.5 (7.7)***	0.12
Pulse, beats/min	-1.9 (16.1)	-1.3 (6.9)	0.88
BIA scale % fat	-1.3 (6.5)	0.4 (2.3)	0.26
Hip circumference, in.	-0.6 (2.8)	0.2 (1.4)	0.27
Waist circumference, in.	-0.2 (1.4)	0.2 (1.6)	0.43
Body Fat Caliper measurement, mm	4.4 (11.7)	0.5 (12.6)	0.30

*Independent samples t-test p-values between group comparisons
**Paired t-test p-value, p<0.05, within group comparisons
*** Paired t-test p-value, p<0.01, within group comparisons

TABLE 4A: HUNGER AND SATIETY VAS SCORES (Baseline)

Question	Active (n=30) Median (Interquartile range)	Placebo (n=34) Median (Interquartile range)	p-value*
Hunger Q1 (How Hungry)			
Time A	28 (16,53)	30 (15,44)	0.74
Time B	49.5 (21,68)	20 (6,46)	**0.004**
Hunger Q2 (Desire to eat)			
Time A	30.5 (17,63)	25.5 (10,38)	0.18
Time B	44 (17,56)	22 (5,38)	**0.004**
Hunger Q3 (How Full)			
Time A	47 (26,60)	57 (50,70)	**0.03**
Time B	50 (34,61)	61 (46,80)	**0.03**
Satiety Q1 (How Satisfied)			
Time A	51 (36,65)	50.5 (44,62)	0.94
Time B	55 (47,80)	54 (50,82)	0.59
Satiety Q2 (How Full)			
Time A	53 (38,75)	59 (49,79)	0.33
Time B	59.5 (50,82)	60 (42,83)	0.82
Satiety Q3 (How much can eat)	48.5 (36,69)	32 (19,52)	0.08
Time A	47.5 (18,53)	23 (10,50)	0.16
Time B			
Satiety Q4 (Desire to eat)			
Time A	47 (19,61)	26 (10,40)	**0.04**
Time B	44.5 (18,54)	17.5 (10,40)	0.04

*Wilcoxon Rank Sum and Fisher's Exact test p-values.
** Signed rank sum t-test p-value, p<0.05
***Signed rank sum t-test p-value, p<0.01

TABLE 4B: HUNGER AND SATIETY VAS SCORES (Week 6)

Question	Active (n=26) Median (Interquartile range)	Placebo (n=24) Median (Interquartile range)	p-value*
Hunger Q1 (How Hungry)			
Time A	27.5 (15,50)	32.5 (15,46)	1.00
Time B	23.5 (8,51)	34.5 (18,49.5)	0.49
Hunger Q2 (Desire to eat)			
Time A	36 (13,46)	30 (11,47.5)	0.93
Time B	21 (10,49)	38 (12.5,51.5)	0.32
Hunger Q3 (How Full)			
Time A	62 (35,75)	57 (41.5,68.5)	0.39
Time B	56.5 (29,80)	54 (29.5,69.5)	0.60
Satiety Q1 (How Satisfied)			
Time A	61 (40,79)	60 (46,73)	0.66
Time B	57 (42,82)	57 (36.5,78.5)	0.92
Satiety Q2 (How Full)			
Time A	60 (46,82)	61.5 (48,75)	0.79
Time B	62.5 (47,83)	58 (48.5,72.5)	0.64
Satiety Q3 (How much can eat)	38.5 (9,52)**	44 (26,62)	0.38
Time A	33.5 (9,57)	43.5 (22,61.5)	0.27
Time B			
Satiety Q4 (Desire to eat)			
Time A	28 (10,51)	34 (21,47.5)	0.67
Time B	25.5 (11,49)	31.5 (18.5,49)	0.49
Week 6 change from baseline	**Median (Interquartile range)**	**Median (Interquartile range)**	
Hunger Q1 (How Hungry)			
Time A	-3.5 (-23,9)	-9 (-20,4)	0.90
Time B	-5 (-30,8)**	3 (-8.5,9)	0.07
Hunger Q2 (Desire to eat)			
Time A	-5.5 (-27,12)	-0.5 (-13.5,10.5)	0.32
Time B	-7.5 (-36,3)**	9 (-2.0,14)	**0.005**
Hunger Q3 (How Full)			
Time A	9.5 (-13,35)	-6 (-16.5,20.5)	0.20
Time B	7 (-12,27)	-5 (-29.5,16.5)	0.09
Satiety Q1 (How Satisfied)			
Time A	4.5 (-12,24)	4 (-13,24)	0.58
Time B	1 (-7,21)	-1.5 (-17,14.5)	0.52
Satiety Q2 (How Full)			
Time A	5.5 (-18,23)	2 (-15,22.5)	0.67
Time B	0.5 (-6,22)	0 (-8.5,26)	0.78
Satiety Q3 (How much can eat)	-5 (-39,5)	2.5 (-14.5,22)	0.08
Time A	-2 (-29,10)	0.5 (-10,13)	0.39
Time B			
Satiety Q4 (Desire to eat)			
Time A	-5 (-46,12)	3 (-12,21.5)	0.13
Time B	-2 (-32,5)	1.5 (-6.5,11)	0.12

*Wilcoxon Rank Sum and Fisher's Exact test. ** Signed rank sum t-test p-value, p<0.05. ***Signed rank sum t-test p-value, p<0.01

TABLE 4C: HUNGER AND SATIETY VAS SCORES (Week 12)

Question	Active (n=22) Median (Interquartile range)	Placebo (n=21) Median (Interquartile range)	p-value*
Hunger Q1 (How Hungry)			
Time A	27 (11,39)	27 (14,45)	0.53
Time B	22 (10,47)	38 (26,58)	0.21
Hunger Q2 (Desire to eat)			
Time A	27.5 (12,45)	28 (19,52)	0.68
Time B	25.5 (13,46)	34 (15,48)	0.64
Hunger Q3 (How Full)			
Time A	56.5 (35,81)	44 (26,60)	0.18
Time B	59 (35,77)	62 (40,73)	1.00
Satiety Q1 (How Satisfied)			
Time A	70 (45,84)	62 (45,70)	0.62
Time B	68.5 (50,85)	60 (49,79)	0.58
Satiety Q2 (How Full)			
Time A	77 (49,88)	50 (32,66)	**0.02**
Time B	70 (49,85)	61 (50,75)	0.70
Satiety Q3 (How much can eat)			
Time A	26 (10,43)	38 (28,52)	0.14
Time B	35.5 (16,52)	32 (20,50)	0.88
Satiety Q4 (Desire to eat)			
Time A	24 (10,40)	35 (15,52)	0.23
Time B	31 (10,56)	32 (10,50)	0.53
Week 12 change from baseline	**Median (Interquartile range)**	**Median (Interquartile range)**	
Hunger Q1 (How Hungry)			
Time A	-5 (-22,4)**	0 (-17,11)	0.34
Time B	-9 (-36,6)**	5 (-8,27)	**0.01**
Hunger Q2 (Desire to eat)			
Time A	-5.5 (-30,12)	-1 (-8,11)	0.21
Time B	-11.5 (-30,5)	4 (-11,16)	**0.03**
Hunger Q3 (How Full)			
Time A	7 (-20,37)	-7 (-26,4)	0.08
Time B	11 (-16,48)	3 (-6,6)	0.26
Satiety Q1 (How Satisfied)			
Time A	5 (-8,26)	3 (-7,19)	0.97
Time B	6 (-24,35)	3 (-2,22)	0.80
Satiety Q2 (How Full)			
Time A	10 (-4,33)**	-6 (-19,6)	**0.02**
Time B	13.5 (-23,28)	12 (4,20)***	0.83
Satiety Q3 (How much can eat)	-19 (-30,-3)***	-3 (-14,7)	**0.05**
Time A	-7.5 (-15,6)	-7 (-13,6)	0.68
Time B			
Satiety Q4 (Desire to eat)			
Time A	-9.5 (-49,1)***	-5 (-9,14)	0.06
Time B	-5 (-16,2)	0 (-24,7)	0.61

*Wilcoxon Rank Sum and Fisher's Exact test. ** Signed rank sum t-test p-value, p<0.05. ***Signed rank sum t-test p-value, p<0.01

TABLE 5A: ENERGY AND MOOD VAS SCORES (Baseline)

Question	Active (n=30) Median (Interquartile range)	Placebo (n=34) Median (Interquartile range)	p-value*
Energy Q1 (How tired now) Time A Time B	36.5 (15,55) 49 (27,64)	37.5 (20,55) 37.5 (22,65)	0.59 0.66
Energy Q2 (How tired past week) Time A Time B	39.5 (22,64) 45 (20,67)	49 (33,56) 50 (31,68)	0.65 0.47
Energy Q3 (How well concentrate now) Time A Time B	71 (53,80) 68 (41,80)	74.5 (52,80) 75 (50,80)	0.62 0.40
Energy Q4 (How well concentrate past week) Time A Time B	64.5 (42,80) 58.5 (35,77)	67 (50,80) 68.5 (45,80)	0.76 0.31
Energy Q5 (How well when up in morning) Time A Time B	41 (19,70) 41.5 (19,65)	50 (16,59) 42.5 (45,80)	0.70 0.56
Mood Q1(How nervous/anxious) Time A Time B	17 (6,45) 14.5 (6,48)	10.5 (16,59) 13 (4,26)	0.21 0.32
Mood Q2(How depressed/blue) Time A Time B	9 (4,49) 10 (5,66)	8.5 (0,25) 9 (0,26)	0.59 0.27

*Wilcoxon Rank Sum and Fisher's Exact test p-values.
** Signed rank sum t-test p-value, p<0.05
***Signed rank sum t-test p-value, p<0.01

TABLE 5B: ENERGY AND MOOD VAS SCORES (Week 6)

Question	Active (n=26) Median (Interquartile range)	Placebo (n=24) Median (Interquartile range)	p-value*
Energy Q1 (How tired now) Time A Time B	20.5 (10,46) 15 (10,45)	21 (11.5,35.5) 32.5 (13.5,58)	0.66 0.25
Energy Q2 (How tired past week) Time A Time B	21.5 (15,38) 16 (9,41)	29.5 (17,40.5) 34 (22,50)	0.46 0.10
Energy Q3 (How well concentrate now) Time A Time B	73 (57,83) 80 (60,84)	75.5 (59.5,80.5) 74 (59.5,83)	0.82 0.52
Energy Q4 (How well concentrate past week) Time A Time B	76 (64,81) 76 (50,84)	73 (59.5,803.5) 73 (56.5,82.5)	0.85 0.98
Energy Q5 (How well when up in morning) Time A Time B	21 (12,45) 20.5 (9,48)	39 (20,51.5) 27 (12,47)	0.32 0.69
Mood Q1(How nervous/anxious) Time A Time B	15.5 (7,26) 12.5 (7,24)	14 (6.5,38) 16.5 (5.5,22.5)	0.82 0.88
Mood Q2(How depressed/blue) Time A Time B	9 (5,13) 9.5 (4,16)	10.5 (5,35) 11 (5,24)	0.41 0.51
Week 12 change from baseline	**Median (Interquartile range**	**Median (Interquartile range**	
Energy Q1 (How tired now) Time A Time B	-9 (-35,7) -17 (-38,1)***	-8 (-34.5,2)** -2 (-18,3)	0.62 0.11
Energy Q2 (How tired past week) Time A Time B	-14.5 (-34,-1)** -23 (-38,-2)***	-13.5 (-30.5,-0.5)*** -17 (-26.5,-7)***	0.85 0.20
Energy Q3 (How well concentrate now) Time A Time B	8 (-2,25) 7 (-3,30)**	3 (-4.5,12) 2 (-3.5,15.5)	0.45 0.48

Table continued in next page

TABLE 5B: ENERGY AND MOOD VAS SCORES (Week 6) – Continued			
Energy Q4 (How well concentrate past week) Time A Time B	17.5 (-1,35)** 5.5 (-14,33)	4 (-6.5,20) 5 (-9,21.5)	0.28 0.70
Energy Q5 (How well when up in morning) Time A Time B	-14.5 (-31,0) -18 (-40,2)	-6 (-38.5,11) -11 (-27.5,5)	0.49 0.58
Mood Q1(How nervous/anxious) Time A Time B	-1 (-12,7) -2 (-19,4)	0 (-9,5.5) -1.5 (-8,2.5)	0.88 0.56
Mood Q2(How depressed/blue) Time A Time B	0.5 (-15,5) -1.5 (-42,0)***	0 (-4.5,2.5) -2 (-8.5,1)**	0.73 0.36

*Wilcoxon Rank Sum and Fisher's Exact test p-values.
** Signed rank sum t-test p-value, $p<0.05$
***Signed rank sum t-test p-value, $p<0.01$

TABLE 5C: ENERGY AND MOOD VAS SCORES (Week 12)

Question	Active (n=22) Median (Interquartile range)	Placebo (n=21) Median (Interquartile range)	p-value*
Energy Q1 (How tired now) Time A Time B	18.5 (11,35) 18.5 (9,39)	27 (7,37) 19 (9,40)	0.83 0.77
Energy Q2 (How tired past week) Time A Time B	25.5 (14.43) 21.5 (10,37)	26 (16,50) 30 (13,47)	0.78 0.38
Energy Q3 (How well concentrate now) Time A Time B	68.5 (52,82) 57.5 (38,85)	77 (58,83) 71 (56,88)	0.30 0.08
Energy Q4 (How well concentrate past week) Time A Time B	68.5 (52,82) 68 (42,84)	60 (48,78) 70 (57,88)	0.40 0.38
Energy Q5 (How well when up in morning) Time A Time B	25 (14,51) 25.5 (7,44)	33 (18,55) 25 (13.53)	0.66 0.66
Mood Q1(How nervous/anxious) Time A Time B	21 (5,44) 11.5 (7,34)	16 (9,44) 13 (8,44)	0.85 0.79
Mood Q2(How depressed/blue) Time A Time B	10.5 (5,19) 13 (5,21)	16 (7,45) 11 (7,52)	0.38 0.73
Week 12 change from baseline	**Median (Interquartile range**	**Median (Interquartile range**	
Energy Q1 (How tired now) Time A Time B	-8 (-37,2) -17 (-54,-5)***	-6 (-23,7)** -15 (-31,8)	0.63 0.20
Energy Q2 (How tired past week) Time A Time B	-14.5 (-36,0)** -27 (-45,-3)***	-5 (-33,2) -6 (-39,4)**	0.52 0.29
Energy Q3 (How well concentrate now) Time A Time B	5 (-21,25) 0.5 (-29,27)	9 (1,17)** 9 (3,16)**	0.55 0.25

Table continued in next page

TABLE 5C: ENERGY AND MOOD VAS SCORES (Week 12) – Continued			
	8 (-6,28) 2 (-6,28)	-1 (-8,20) 10 (0,19)	0.33 0.54
Energy Q5 (How well when in morning) Time A Time B	-15.5 (-36,0)** -20.5 (-37,-4)**	-5 (-37,8)** -3 (-25,10)	0.68 0.20
Mood Q1(How nervous/anxious) Time A Time B	-0.5 (-8,19) -2.5 (-22,0)	0 (-8,7) 0 (-12,13)	0.88 0.24
Mood Q2(How depressed/blue) Time A Time B	-0.5 (-19,6) 0 (-30,6)	0 (-6,5) -1 (-7,2)	0.79 0.56

*Wilcoxon Rank Sum and Fisher's Exact test p-values.
** Signed rank sum t-test p-value, p<0.05
***Signed rank sum t-test p-value, p<0.01

TABLE 6A: COMPREHENSIVE METABOLIC PANEL (Baseline)

Test	Active (n=36) Mean (SD)	Placebo (n=35) Mean (SD)	p-value*
Sodium	138.4 (21.4)[2]	137.6 (2.0)	0.16
Potassium	4.3 (0.4)	4.4 (0.4)	0.45
Chloride	104.5 (2.2)	104.3 (2.2)	0.64
Carbon dioxide	26.1 (2.9)	25.7 (3.2)	0.59
Glucose	88.4 (13.9)	88.1 (12.5)	0.90
BUN	12.8 (3.1)	14.2 (4.8)	0.17
Creatinine	0.84 (0.19)	0.86 (0.21)	0.66
BUN creatinine ratio	16.0 (5.0)	16.7 (4.5)	0.55
Calcium	9.6 (0.4)	9.5 (0.4)	0.23
Total protein	7.1 (0.4)	7.1 (0.4)	0.82
Albumin	4.3 (0.2)	4.3 (0.2)	0.79
Total bilirubin	0.52 (0.19)	0.51 (0.21)	0.77
ALK phosphatase	67.8 (20.0)	61.4 (17.9)	0.16
SGOT (AST)	21.5 (11.6)	20.7 (14.8)	0.81
SGPT (ALT)	21.2 (13.7)	23.4 (23.7)	0.64
Globulin	2.8 (0.4)	2.8 (0.4)	0.66
A/G ratio	1.5 (0.2)	2.0 (2.5)	0.29

*Independent samples t-test p-values

TABLE 6B: COMPREHENSIVE METABOLIC PANEL (Week 12)

Test	Active (n=36) Mean (SD)	Placebo (n=35) Mean (SD)	p-value*
Sodium	138.7 (1.7)	137.2 (1.9)	**0.01**
Potassium	4.7 (0.6)	4.6 (0.5)	0.74
Chloride	104.1 (1.7)	103.4 (1.5)	0.20
Carbon dioxide	26.0 (3.1)	25.4 (2.8)	0.58
Glucose	89.9 (14.7)	89.5 (13.8)	0.93
BUN	12.8 (2.8)	12.8 (3.8)	1.00
Creatinine	0.85 (0.14)	0.88 (0.22)	0.61
BUN creatinine ratio	15.2 (3.5)	14.7 (3.3)	0.63
Calcium	9.8 (0.4)	9.6 (0.4)	0.18
Total protein	7.3 (0.4)	7.3 (0.4)	0.74
Albumin	4.4 (0.2)	4.3 (0.2)	0.24
Total bilirubin	0.53 (0.22)	0.54 (0.13)	0.91
ALK phosphatase	71.3 (23.2)	64.9 (18.2)	0.36
SGOT (AST)	22.2 (11.3)	21.8 (10.5)	0.92
SGPT (ALT)	23.0 (14.7)	25.7 (16.3)	0.59
Globulin	2.9 (0.4)	3.0 (0.4)	0.31
A/G ratio	1.6 (0.2)	1.5 (0.2)	0.22

*Independent samples t-test p-values

TABLE 7: GLOBAL EVALUATION QUESTIONNAIRE

Question	Active (n=22)	Placebo (n=21)	p-value*
Q1: Product helped them lose weight, Yes n (%)	9 (40.9%)	8 (38.1%)	0.85
Q2: Product increased their energy, Yes n (%)	13 (59.1%)	11 (52.4%)	0.66
Q3: Which product do you believe you were taking?	Active 12 (54.6%) Placebo 10 (45.4%)	Active 14 (66.7%) Placebo 7 (33.3%)	0.42
Q4: The product well tolerated, Yes n (%)	22 (100%)	20 (96.2%)	0.30
Q5: Would take this product again, Yes n (%)	15 (68.2%)	11 (52.4%)	0.29

*Chi-square test p-values

TABLE 8: NUMBER OF TIMES EXERCISED

Time interval	Active (n=23) Mean (SD)	Placebo (n=25) Mean (SD)	p-value*
Week 6	4.4(1.5)	4.3 (1.1)	0.74
Week 12	4.6 (1.3)	4.3 (1.5)	0.43
Total over weeks 1 – 12	53.5 (13.6)	48.6 (17.5)	0.29

*Independent samples t-test p-values

TABLE 9: SUBJECT REPORTED SIDE EFFECTS

Week 6	Active (n=25)	Placebo (n=25)	p-value[1]
1. Nausea	3	1	0.61
2.Flushing	1	0	1.00
3.Feeling hot	3	3	1.00
4.Somnolence (sleepiness)	4	3	1.00
5.Headache, any	3	4	1.00
6.Headache, more than normal	1	3	0.61
7.Excessive sweating	4	3	1.00
8.Insomnia, difficulty falling asleep	4	3	1.00
9.Insomnia, difficulty staying asleep	3	5	0.70
10.Any other side effects	1	1	1.00
Total subjects with side effects – week 6	11 (44.0%)	14 (56%)	0.40
Week 12	**Active (n=25)**	**Placebo (n=21)**	**p-value**
1. Nausea	1	1	1.00
2.Flushing	1	0	1.00
3.Feeling hot	4	1	0.35
4.Somnolence (sleepiness)	1	6	0.04
5.Headache, any	3	4	0.69
6.Headache, more than normal	3	1	0.61
7.Excessive sweating	3	2	1.00
8.Insomnia, difficulty falling asleep	2	3	0.65
9.Insomnia, difficulty staying asleep	2	4	0.40
10.Any other side effects	1	0	1.00
Total subjects with side effects – week 12	7 (29.2%)	9 (42.9%)	0.34

*Chi-square and Fisher's Exact test p-values

8. APPENDICES

APPENDIX 1: HUNGER AND SATIETY VAS QUESTIONNAIRE

Patient #_____

Adapted From Flint et al 2001
100mm lines

Hunger		
I am not hungry at all	How hungry do you feel?	I have never been more hungry
I am not hungry at all	How strong is your desire to eat right now?	I have never been more hungry
Not at all full	How full does your stomach feel at this moment?	Extremely full
Satiety		
I am completely empty	How satisfied do you feel?	I cannot eat another bite
Not at all full	How full do you feel?	Totally full
Prospective Consumption		
Nothing at all	How much do you think you can eat?	A lot
I am not hungry at all	How strong is your desire to eat right now?	I have never been more hungry

APPENDIX 2: ENERGY AND MOOD ASSESSMENT VAS QUESTIONNAIRE

Patient #_____

(VAS 100mm lines)

Energy Level		
I am not tired at all	How tired do you feel at this moment?	I have never been more tired
I was not tired at all	How tired have you felt during the past week?	I was never more tired
I cannot concentrate at all	How well do you feel you can concentrate at this moment?	I can concentrate very well
I could not concentrate at all	How well did you feel you could concentrate during the past week?	I could concentrate very well
Awoke well and rested	How have you felt when you get up in the morning?	Awoke very tired

Mood		
I am not anxious or nervous at all	How nervous or anxious have you felt?	I have never been more anxious or nervous
I am not depressed at all	How depressed or blue have you felt?	I have never been more depressed