

JEPonline
Journal of Exercise Physiologyonline

**Official Journal of The American
Society of Exercise Physiologists (ASEP)**

ISSN 1097-9751

An International Electronic Journal
Volume 4 Number 2 May 2001

Body Composition

**THE EFFECT OF COMMERCIAL THERMOGENIC WEIGHT LOSS SUPPLEMENT ON
BODY COMPOSITION AND ENERGY EXPENDITURE IN OBESE ADULTS**

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ABSTRACT

W. JEFFREY ARMSTRONG, PATRICK JOHNSON AND SIMONE DUHME. **The Effect Of Commercial Thermogenic Weight Loss Supplement On Body Composition And Energy Expenditure In Obese Adults.** *JEPonline*. 2001;4(2):28-34. The purpose was to determine the effects of an herbal preparation containing ma huang, bitter orange and guarana on resting energy expenditure (REE), blood chemistries, and body composition in obese adults. Five males and 15 females (age=31±6 yr, height=168.1 ±4 cm, weight=93.4±7.1 kg, %fat=43.8 ±5%) were matched, randomly assigned to either the supplement (N=12) or placebo (N=8) group, and participated in a 44 d aerobic exercise program (3 d/wk). REE was determined by open-circuit spirometry, and serum samples were analyzed for glucose, cholesterol, triglycerides, HDL, and LDL. Changes in body mass (BM), %fat, fat mass (FM), and fat-free mass (FFM) were determined using DEXA. Due to limited compliance, pre- and post-treatment diet recalls were analyzed for only 14 subjects (supplement=9, placebo=5). Analysis included doubly MANOVA repeated measures (diet recalls and blood chemistries) and independent *t*-tests (REE and body composition) at $\alpha < 0.05$. The only significant difference was in FM ($p=0.033$). When a more liberal alpha ($\alpha < 0.10$) is considered, %fat and BM were significant ($p=0.096$ and 0.087). The supplement, thus, may result in reductions in FM, %fat and BM, but has little effect on energy expenditure, diet or blood chemistries following a six-week period of supplementation and training.

Key Words: Cholesterol, Dexa, Energy Expenditure, Ephedrine, Exercise, Glucose, Ma Huang, Triglycerides, Weight Loss

INTRODUCTION

Obesity is becoming increasingly prevalent in the United States (5). Because it is an established risk factor in hypertension, non-insulin-dependent diabetes mellitus, hyperlipidemia, and atherosclerosis, finding effective

treatments for this disease is imperative. Obesity is often considered to be the product of inactivity and over-eating. However, simplistic understanding of obesity fails to consider more complex issues of this disease such as genetics, psychology, and behavior. Obesity may also involve diminished sympathetic nervous system regulation of thermogenesis (15).

Recent research indicates that ephedrine, a sympathomimetic compound, may have some anti-obesity properties (1). It has been shown to increase energy expenditure in humans (1, 14) and rhesus monkeys (13). When combined with caffeine and a restricted diet it may have an even greater effect on improving and maintaining body composition (3, 6, 13, 16). Daly and co-workers support a strategy of combining low doses of ephedrine, caffeine, and aspirin for sympathomimetic stimulation of thermogenesis (6). Large doses of ephedrine may, though, present substantial risk to the patient (2, 4, 7, 8, 9). Reported risks include nephrolithiasis (2), psychiatric disturbances (9), manic-like symptoms (7), seizures, cardiovascular events, and even death (4). Thus, low doses of several agents may minimize toxicity (6).

Ephedrine enhances the release of norepinephrine (NE) from the sympathetic nerve terminal. As NE levels increase, however, the thermogenic response may be limited by the release by the stimulated tissue of adenosine and prostaglandins (PG), which act as prejunctional inhibitors (6). Caffeine and aspirin may remove these inhibitions by antagonizing adenosine and phosphodiesterases and inhibiting PG synthesis, respectively, thereby increasing and sustaining NE activation of the effector cell (6).

Ephedrine may affect appetite. It has been reported to decrease food consumption in obese rhesus monkeys (13). Daly and associates (6), on the other hand, observed no difference in self-reported appetite between human subjects taking an ephedrine-caffeine-aspirin combination. Likewise, Pasquali and co-workers (11) noted a lack of anorectic effect. Neither group, however, reported any statistical analysis.

The purpose of the present study was to examine the effects of one particular commercially available preparation (Xenadrine RFA-1, Cytodyne Technologies, Lakewood, NJ) containing *ma huang*, a botanical from of ephedrine, and guarana extract (caffeine) on body composition, resting energy expenditure, and appetite while combined with moderate aerobic activity.

Methods

Subjects

Twenty-six subjects (20 females and 6 males) were recruited from the student, staff, and faculty populations at Eastern Michigan University and the surrounding community by word of mouth, flyers, and advertisements in the school newspapers. The subjects were matched according to age, gender, height, weight, and body fat and randomly assigned to receive either the supplement (Suppl, n=13) or a placebo (Placebo, n=13) according to the dosing sequence below. Among these, six (5 females and 1 male) dropped from the study for various reasons. The male (Placebo) and one female (Suppl) subject withdrew with concerns over potential side effects. The others (4 females, Placebo) withdrew for unrelated reasons. Thus, a total of 20 subjects completed the study (Suppl, n=12; Placebo, n=8). All were apparently healthy, and free of contraindications to exercise as determined by a self-reported medical history. Informed consent was obtained before participation and the Eastern Michigan University College of Education Human Subjects Review Committee approved all procedures. The subject demographics are reported in Table 1, and inclusion/exclusion criteria are listed in Table 2.

Table 1. Physical Characteristics of Subjects (mean±SD)

<i>Group (N)</i>	<i>Age (yr)</i>	<i>Height (cm)</i>	<i>Body Weight (kg)</i>	<i>Fat (%)</i>
<i>Supplement (12)</i>	31.3±7.5	165.9±7.4	91.6±16.1	44.8±4.8
<i>Placebo (8)</i>	30.4±5.4	172.0±8.9	96.1±19.2	42.4±8.5
<i>Combined (20)</i>	31.0±6.6	168.1±8.4	93.4±17.1	43.8±6.5

Table 2. Inclusion and Exclusion Criteria***Inclusion criteria:***

- 1) *age 18-40 years*
- 2) *>20% fat for males and >30% fat for females (as determined using dual-energy x-ray absorptiometry, DEXA)*
- 3) *sedentary to moderately active (aerobic activity <3 d/wk)*
- 4) *informed consent*

Exclusion criteria:

- 1) *pregnant or desiring to get pregnant*
- 2) *lactating*
- 3) *orthopedic problems*
- 4) *considerable amount of weight loss (>30 lb) during previous three months*
- 5) *use of weight loss supplements during previous three months*
- 6) *hypertensive (>140/90 mm Hg)*
- 7) *history of heart, liver, thyroid, or psychiatric disease, diabetes, anemia, nervousness, anxiety, depression, seizure disorder, stroke*

Treatment

The supplement, Xenadrine RFA-1 (Cytodyne Technologies, Lakewood, NJ) and placebo were of like characteristics and distribution (Table 3). For the first two days of supplementation the subjects each took one capsule before breakfast (approximately 8-9 AM) and one capsule before the afternoon meal (approximately 2-3 PM). Thereafter, the number of capsules increased to two for both the AM and PM administrations throughout the 44-day supplementation period.

Table 3. Ingredient Content of Supplement and Placebo (per two capsule dose)***Supplement (Xenadrine RFA-1, Cytodyne Technologies, Lakewood, NJ):***

- ♦ *pantothenic acid (40 mg)*
- ♦ *bitter orange (85 mg, standardized for 5 mg synephrine)*
- ♦ *ma huang (335 mg, standardized for 20 mg ephedrine)*
- ♦ *guarana extract (910 mg, standardized for 200 mg caffeine)*
- ♦ *white willow bark extract (105 mg, standardized for 15 mg salicin)*
- ♦ *ginger root (50 mg)*
- ♦ *proprietary ThermoSynergist Blend (225 mg, contains L-Tyrosine, Acetyl L-carnitine, Fisetin, Magnesium Phosphate, DMEA).*

Placebo:

- ♦ *cellulose*
- ♦ *like supplement in appearance and distribution*

Testing

Pre- and post-testing consisted of two sessions each. In the morning of the testing day, the subject reported to the applied physiology laboratory between 6 and 10 AM. The subject lay supine, quietly, with the eyes closed on a padded table in a dimly lit, quiet room for 10 to 15 min. After this time they were fitted with a mouthpiece, expired gases were recorded for 5 min, and daily resting energy expenditure (REE) was determined from the fifth minute using open-circuit spirometry (Vmax, Sormedics, Yorba Linda, CA) and is reported relative to body weight (kcal/kg/d). Heart rate, blood pressure, and single-lead electrocardiogram were recorded as precautionary measures and were not statistically analyzed.

Following the REE measures, 5 ml of blood was collected by venopuncture of an antecubital vein or the dorsum of the hand. Serum was separated and assayed for glucose (GLU), cholesterol (CHOL), triglycerides

(TRIG), and high-density lipoprotein cholesterol (HDL) by the Clinical Laboratory Sciences Department at Eastern Michigan University. Low-density lipoprotein cholesterol was calculated using the following equation:

$$LDL = CHOL - HDL - (TRIG/5).$$

Body composition was measured during the afternoon session in the DEXA (Prodigy model, Lunar Radiation Corporation, Madison, WI) laboratory of the Radiology Department at St. Joseph Mercy Hospital in Ypsilanti, Michigan by trained technicians under the supervision of a physician. This provided data for total body mass (BM), percent fat (%fat), fat mass (FM), and fat-free mass (FFM). DEXA provides a precise, three-compartment analysis with a low radiation exposure (10). It is considered to be a viable tool for measuring body composition (10,12) with precision errors for total body bone mineral density (BMD), %fat, FM, and FFM less than 0.01 g/cm², 1.4%, 1.0 kg, and 0.8 kg, respectively (10).

Because the supplement being studied is purported to have a suppressive effect on the appetite, subjects were asked to record a 3-day dietary recall on a weekly basis. As a result of limited compliance, pre-post data were available for only 14 subjects (Suppl=9, Placebo=5). These were analyzed for three-day averages of total caloric intake (KCAL), total protein (PROT), total carbohydrate (CHO), and total fat (FAT) using Nutritional Software Library™ (Compnutrition, Chatsworth, CA).

Exercise Training Protocol

The aerobic exercise was conducted on the indoor track at Eastern Michigan University during one of three monitored sessions (6-9 AM, 11 AM to 1 PM, or 5-7 PM). The first week following pre-testing consisted of two pre-conditioning walks of 1.5 miles at a comfortable pace (brisk, but not exhaustive). This distance was increased to 2.0 miles three days per week for the duration of the training and subjects were permitted to build up to a jog, if desired. If the subject was unable to attend a scheduled session, he/she was encouraged to make up the session independently. While make-up sessions could not be verified, the researchers did follow-up with the subject and accepted their word that the session was performed.

Data Analysis

The SPSS 10.0 for Windows statistical package was used for all statistical analyses. Differences pre-to-post in REE relative to body weight (REE/BM), BM, %fat, FM, and FFM were compared using independent *t*-tests. The three-day diet recall data and blood chemistries were analyzed using doubly MANOVA repeated measures to determine whether there were significant effects for time and group by time for the linear combination of the dependent variables. The data are reported as mean ± S.D. and Student's *t*-tests were used to compare initial group differences for age, BM, height, and %fat. In addition, effect sizes (*d*) for the dependent variables were calculated based upon means and standard deviations obtained from the pre- and post-treatment Suppl data (Table 4). Significance was set at a α -level of 0.05 for all analyses.

RESULTS

Pre-training Data

The mean (±SD) age, height, body weight, and percent fat were 31.0 ± 7.5 yr, 168.3 ± 8.4 cm, 93.4 ± 17.1 kg, and 43.8 ± 6.5 %, respectively. Although the Placebo was slightly taller, heavier and leaner than Suppl (Table 1), the groups did not differ significantly at the start of the study (*p*= 0.769, 0.117, 0.577, and 0.421, respectively).

REE and Body Composition Measures

The pre- and post-supplementation REE/BM and body composition data for both groups are

Table 4. Effect Sizes (*d*) for Dependent Variables

<i>Variable</i>	<i>d</i>
<i>REE/BM (resting energy expenditure/body mass)</i>	0.37
<i>BM (body mass)</i>	0.09
<i>%fat (percent body fat)</i>	0.43
<i>FM (fat mass)</i>	0.26
<i>FFM (fat-free mass)</i>	0.12
<i>KCAL (kilocalories)</i>	0.13
<i>CHO (carbohydrates)</i>	0.05
<i>PROT (proteins)</i>	0.25
<i>FAT (fats)</i>	0.26
<i>GLUC (blood glucose)</i>	0.15
<i>CHOL (total cholesterol)</i>	0.48
<i>TRIG (triglycerides)</i>	0.19
<i>HDL (high-density lipoprotein cholesterol)</i>	0.04
<i>LDL (low-density lipoprotein cholesterol)</i>	0.49

shown in Table 5. Independent *t*-tests revealed that the only significant difference between groups at $\alpha < 0.05$ was FM ($P = 0.688, 0.087, 0.096, 0.033, 0.554$ for REE/BM, BM, %fat, FM, FFM, respectively).

Table 5. Mean Energy Expenditure and Body Composition Measures (\pm SD)

Variable	REE/BM (kcal/kg/d)		%Fat (%)§		BM (kg) §		FM (kg)*		FFM (kg)	
	pre	post	pre	post	pre	post	pre	post	pre	post
SUPPL (N = 12)	17.77 (2.86)	19.22 (4.97)	44.82 (4.81)	42.47 (6.21)	91.63 (16.13)	90.18 (16.33)	41.22 (9.33)	38.65 (10.67)	47.66 (8.71)	48.74 (8.55)
PLACEBO (N = 8)	18.00 (2.70)	18.35 (2.71)	42.38 (8.53)	41.76 (8.43)	96.14 (19.20)	96.36 (20.85)	41.09 (13.59)	40.60 (14.09)	51.89 (11.25)	52.56 (11.91)

* $P \leq 0.05$; § $P \leq 0.10$

Diet Analysis

The pre- and post-supplementation diet recall data for both groups are shown in Table 6. Using MANOVA, there was no significant change in the subjects' diets over the supplementation period ($P = 0.129$), nor was there a significant difference between groups for KCAL, PROT, CHO, and FAT combined ($p=0.622$).

Table 6. Mean Dietary Intakes (\pm SD)

Variable	KCAL		PROT (g)		CHO (g)		FAT (g)	
	pre	post	pre	post	pre	post	pre	post
SUPPL (N=9)	2251.00 (1107.50)	2140.00 (618.51)	98.24 (44.64)	88.71 (30.35)	278.21 (137.40)	272.47 (115.10)	81.89 (48.25)	72.00 (26.56)
PLACEBO (N=5)	2440.20 (587.58)	2134.80 (764.12)	87.04 (26.52)	74.08 (10.18)	311.18 (73.59)	315.54 (134.33)	97.60 (33.19)	66.14 (43.36)

Blood Chemistries

The pre- and post-supplementation blood chemistry data for both groups are shown in Table 7. Using MANOVA, there was no significant change in the subjects' blood chemistries over the supplementation period ($p=0.094$), and there was no significant difference between groups for GLUC, CHOL, TRIG, HDL, and LDL combined ($p=0.775$).

Table 7. Mean Blood Chemistry Measures (\pm SD)

Variable	GLUC (mg/dl)		CHOL (mg/dl)		TRIG (mg/dl)		HDL (mg/dl)		LDL (mg/dl)	
	pre	post	pre	post	pre	post	pre	post	pre	post
SUPPL (N=12)	85.17 (11.18)	87.33 (16.85)	181.50 (20.86)	170.67 (24.67)	121.42 (62.67)	136.67 (100.65)	35.92 (8.12)	35.58 (7.29)	121.83 (25.70)	107.67 (32.06)
PLACEBO (N=8)	79.75 (7.23)	87.12 (4.61)	166.38 (20.20)	159.88 (23.50)	81.75 (55.43)	96.25 (68.65)	40.12 (8.25)	35.62 (6.07)	110.62 (17.28)	105.00 (17.21)

DISCUSSION

The present study was initiated to ascertain whether six weeks of supplementation of a commercially available thermogenic weight loss supplement (Xenadrine RFA-1) would affect body composition, appetite, and resting energy expenditure in obese men and women. Previous research has indicated that botanical ephedrine (*ma huang*) increases resting energy expenditure in obese rhesus monkeys (13) and humans (1,12). Likewise, ephedrine is reported to facilitate weight loss in obese rhesus monkeys (13). When combined with caffeine the effects appear to be magnified (16). The addition of aspirin has also been proposed (6).

The supplement, Xenadrine RFA-1, is standardized to doses of 20 mg of botanical ephedrine (*ma huang*) and 200 mg of caffeine (guarana extract) per 2 capsule dose. According Gurley et al. (8), the pharmacokinetics of botanical ephedrine are similar to those of synthetic ephedrine. Thus, the content of *ma huang* contained within

the product tested is consistent with the treatments used in the reviewed studies. When the effect ephedrine alone in human subjects was examined, doses were 10, 20, and 40 mg (1), 25 and 50 mg (11), or 50 mg three times a day (14). Combined doses of ephedrine and caffeine were 20 mg and 200 mg (16). Unlike the previous research, Xenadrine RFA-1 contains an additional sympathomimetic agent, bitter orange (standardized for 5 mg synephrine).

It was expected that the ingested dosage would promote changes in body composition. The only change of statistical significance was FM ($p=0.033$). There was, however, a modest decrease in BM and %fat for subjects taking the supplement ($p=0.087$ and 0.096 , respectively). This is comparable to Daly and associates (6), who reported a significantly greater mean cumulative weight loss in subjects taking an ephedrine/caffeine/aspirin combination (-1.8 kg vs 0.5 kg). These changes may have been offset by variable increases in FFM (-2.38 kg to +4.03 kg). All but four subjects lost fat mass (1 Suppl and 3 Placebo), whereas only 12 subjects gained lean mass (7 Suppl and 5 Placebo or 58.3% and 62.5%, respectively). Hence, while the supplement may promote fat loss, its effect on lean mass is equivocal.

That resting energy expenditure relative to body weight did not increase during the supplementation period may not be inconsistent with previous research. While Shannon and co-workers (14) observed an increase in mean 24-hr energy expenditure, but not in basal metabolic rate determined between 6:30 and 7:30. This measure was recorded approximately 11-12 h following the last dose of ephedrine. In the present study, post-supplementation resting energy expenditure was determined after a much longer period. Subjects ingested their final dose in the afternoon prior to the testing session, which was scheduled between 6:00 and 10:30. This may have been sufficient time for the effects of the supplement to diminish.

It must also be considered that the method used to measure REE is not without limitations. Breathing through a mouthpiece allows for only a brief sample of expired gases while the subject is awake, but relaxed. Additionally, such an apparatus may affect sympathetic activity (14). Ideally, a metabolic chamber should be used for extended sampling.

Analysis of serum glucose, cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol revealed no effect of supplementation. This is consistent with the results reported by Daly and associates (6). These researchers observed no change in glucose, insulin, cholesterol, and HDL cholesterol after 8 wk supplementation of an ephedrine/caffeine/aspirin mixture. While there seems to be no benefit on these components of the blood, it may be noted that there were no negative effects observed in the blood.

Diet analysis also failed to indicate any effect of intake of energy, protein, carbohydrate, or fat. This is consistent with Daly et al. (6) who also observed no significant differences in self-reported appetite. Compliance was an issue, however. Of the 20 subjects studied, only 7 completed all of the requested recalls. Only the pre- and post-supplementation recalls were analyzed ($N = 14$) in order to maximize the observed power.

Another consideration regarding the failure to observe changes in appetite is that recall of food consumed may not be a sufficient measure of hunger in obesity. Obesity involves complex psychological factors, as well as physiological and behavioral factors. At the conclusion of the study, one subject expressed awareness of a pattern of disordered eating. Differing schedules may affect how much was eaten from day to day and subject to subject. The quantity of food eaten may also be linked to habit or emotional need rather than physical need. Therefore, a different approach to measuring appetite should be considered.

Side Effects

While side effects were not measured directly, close attention was paid to any adverse affect of the supplementation. Of the subjects who started on the supplement, only two noted any discomfort. One (female) reported heightened anxiousness and elevated heart rate during the first few days of the study. These symptoms

soon passed and the subject continued unaffected. One subject, however, did excuse herself from the study because she was uncomfortable with the elevated heart rate and feeling of “warmed blood.” Such reactions to products such as the one tested are not uncommon. Previous researchers have reported side effects such as dry mouth, jitters, and constipation (1, 6, 11, 16), headache and insomnia (11, 16) in a few subjects while others have reported more severe side effects such as vomiting, abdominal pain, and tremor (3) nephrolithiasis (2), psychological disorders (7, 9), seizures, cardiovascular events, and death (4). Of the studies reviewed, however, only Cupps (4), Gurley et al. (8), and Jacobs and Hirsch (9) speak to herbal ephedrine (ma huang). In most cases, the symptoms are mild and reported to disappear within a month. Gurley and co-workers (8) suggest that severe cases of ma huang toxicity tend to be associated with abuse of the supplement. Therefore, close attention to the manufacturers precautions and to unusual symptoms should be stressed.

Statistical Power

Effect sizes for the dependent variables (Table 4) are small-to-moderate (0.09 to 0.49). Hence, the ability to detect real differences is limited by a small sample size. The ability to detect changes in REE/BM, %fat, and FM, in particular, may have suffered. Given these effect sizes ($d = 0.37, 0.43, \text{ and } 0.26$, respectively), a sample size in excess of 90 subjects per group is required to obtain power of at least 0.80 (17). In addition, tighter controls over diet analysis and the measurement of appetite is necessary.

Suggestions for Future Research

While this study may indicate some positive effect of ephedrine/caffeine supplementation on body weight and percentage fat, further research is needed to more clearly examine the safety and efficacy a thermogenic weight loss supplement such as the one studied. A longer training period may be necessary. Toubro and co-workers (16) observed a significant weight loss in subjects treated with ephedrine plus caffeine only after eight weeks. As well, more precise measurement of energy expenditure over a longer period of time is recommended. Diet recall should be more tightly overseen and some measure of appetite level should be included.

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