CONSUMING A MULTI-INGREDIENT THERMOGENIC SUPPLEMENT FOR 28 DAYS IS APPARENTLY SAFE IN RECREATIONALLY ACTIVE ADULTS

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ABSTRACT

Increased awareness of the health risks associated with overweight and obesity has sparked interest in finding effective weight loss strategies. Thermogenic (TRM) supplements are often viewed as a viable option for those looking to decrease body weight or fat mass. Many TRM supplements are formulated with multiple ingredients purported to increase energy expenditure, suppress appetite, or both. Stimulants such as caffeine anhydrous and green tea extract are often combined to achieve these effects. However, as has been the case in the past, some of the most efficacious ingredients can pose a significant health risk to certain populations, and have subsequently been removed from the market. With this in mind, it is important to verify the safety and potential side effects of TRM supplements with chronic consumption. PURPOSE: To assess the safety of daily consumption of a multi-ingredient TRM supplement over a period of 28 days in healthy men and women. Methods: 23 recreationally active men and women (11 male, 12 female; 27.1 ± 5.4 y, 171.6 ± 9.6 cm, 76.8 ± 16.1 kg) participated in this simple randomized study. Participants were assigned either to consume 2 servings daily of a multi-ingredient TRM supplement (SUP; n = 9) or remain unsupplemented (CRL; n = 14) for 28 days. All were instructed to maintain their habitual dietary and exercise routines for the duration of the study. Fasting blood samples, as well as resting blood pressure and heart rate, were taken prior to and following the supplementation period. Samples were analyzed for complete blood counts, comprehensive metabolic, and lipid panels. Results: Significant ($p < 0.05$) group by time interactions were present for diastolic blood pressure, creatinine, eGFR, chloride, CO2, globulin, albumin:globulin ratio, and HDL cholesterol. Each of these variables remained within the accepted physiological range. Data are presented as means ± SD in Table 1. No other variables had significant interactions ($p > 0.05$). Conclusion: The present study confirms the hypothesis that chronic daily consumption of a multi-ingredient TRM will not cause adverse changes in hematological markers of clinical safety or resting vital signs in healthy adults. Although there were statistically significant ($p < 0.05$) group by time interactions for diastolic blood pressure, creatinine, eGFR, chloride, CO2, globulin, albumin:globulin ratio, and HDL cholesterol, all of the results remained well within accepted physiological ranges and were not clinically significant. In sum, it appears as though daily supplementation with up to 2 servings of a TRM has no adverse effects on markers of clinical safety among healthy adults for a period of 28 days. Practical Applications: For healthy individuals or athletes looking to supplement to possibly help reduce body fat or mass, the multi-ingredient TRM in the present study appears to be safe for chronic consumption.

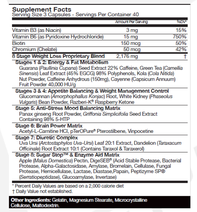
BACKGROUND

Over the past decade, the prevalence of overweight and obesity in the United States has continued to rise, with approximately two-thirds of the adult population fitting into these categories (1). As the health risks associated with overweight and obesity have become apparent (2), many individuals are attempting to either control or lose weight (3). Thermogenic (TRM) supplements are often viewed as a viable option for those looking to decrease body weight or fat mass. Many TRM supplements are formulated with multiple ingredients purported to increase energy expenditure (EE), increase fat oxidation, or suppress appetite. Stimulants such as caffeine anhydrous and green tea extract are often combined to achieve these effects. However, caution must also be exercised when considering TRM supplements that combine multiple putative ingredients. As has been the case in the past, some of the most efficacious TRM ingredients have been deemed unsafe for consumption and subsequently removed from the market by the Food and Drug Administration. Ephedra and 1,3-dimethylamylamine (DMAA) provide two such examples, wherein the potential benefits associated with the products were outweighed by evidence of a significant health risk posed to consumers (4,5). It is therefore prudent to verify the safety and potential side effects of TRM supplements currently on the market. The purpose of the present study was to assess the clinical safety of daily consumption of a multi-ingredient TRM supplement containing caffeine, green tea extract, and capsaicin-containing cayenne fruit powder over a period of 28 days in healthy men and women. It was hypothesized that daily supplementation would not produce abnormal changes in hematological or metabolic safety markers or resting vital signs.

METHODS

In a randomized design, 23 subjects (12 female, 11 male) were assigned to control (CRL, n = 14; 26.5 ± 5.9 y, 173.6 ± 9.1 cm, 77.0 ± 17.8 kg, 25.4 ± 4.8 BMI) or supplement (SUP, n = 9; 28.0 ± 4.7 y, 168.5 ± 10.0 cm, 76.6 ± 14.2 kg, 27.1 ± 5.3 BMI) groups and asked either to remain unsupplemented or consume 2 servings, respectively, of a commercially available TRM (MuslcePharm Shred Matrix™, MusclePharm Inc., Denver, CO, USA) every day for 28 days. Supplement facts are listed in Figure 1. Subjects in SUP were instructed to consume 1 serving (3 capsules) of the TRM in the morning 30-45 minutes prior to breakfast with at least 8 oz water, as well as 1 serving (3 capsules) 30-45 minutes prior to lunch with at least 8 oz water. Compliance was monitored using supplement consumption logs, as well as by quantifying the number of capsules in the supplement containers before and after the supplementation period. Participants completed the study with an average supplementation compliance of 96.5%. Blood draws were taken prior to and following the supplementation period. Approval for the human subject protocol was obtained from a registered IRB, and subjects provided written informed consent prior to their participation in the study.

Figure 1. Supplement Facts



Supplement Facts
Serving Size 3 Capsules - Servings Per Container 40

	Amount Per Serving	%DV
Vitamin B3 (as Niacin)	3 mg	15%
Vitamin B6 (as Pyridoxine Hydrochloride)	15 mg	750%
Biotin	150 mcg	50%
Chromium (Chelate)	200 mcg	167%
† Stage Weight Loss Proprietary Blend	2,175 mg	**
Stagite † E 2: Energy & Fat Metabolism Guarana (Paullinia Cupana) Seed Extract (21% Caffeine, Green Tea (Camellia Sinensis) Leaf Extract (45% EGCG) 98% Polyphenols, Kola (Cola Nitida) Seed Extract, Caffeine Anhydrous (150mg), Cayenne (Capsicum Annuum) Fruit Powder, Q10(Ubiquinone)		
Stagite 3 & 4: Appetite Balancing & Weight Management Content Glucomannan (Amorphophallus Konjac) Root, White Kidney (Phaseolus Vulgaris) Bean Powder, Rspberry® Raspberry Ketone		
Stage 5: Anti-Stress Mood Balancing Matrix Panax ginseng Root Powder, Griffonia Simplicifolia Seed Extract (Griffonia Seed 5-HTP)		
Stage 6: Brain Power Matrix Acetyl-L-Carnitine HCl, pTerC®Pure® Pterostilbene, Vinpocetine		
Stage 7: Diuretic Complex Uva Ursi (Arctostaphylos Uva-Ursi) Leaf 25:1 Extract, Dandelion (Taraxacum Officinale) Root Extract, Juniper (Juniperus Spp.) Berries & Taraxerol		
Stage 8: Super Stag™ 8 Enzyme Anti Meal Apple (Malus Domestica) Pectin, DigestEZ® (Acid Stable Protease, Bacterial Protease, Alpha-Galactosidase, Amylase, Bromelain, Cellulase, Fungal Protease, Hemicellulase, Lactase, Cleistase,Papain, Peptizyme SP® (Serratiopeptidase), Glucoamylase, Invertase)		

* Percent Daily Values are based on a 2,000 calorie diet
† Daily Value not established.

Other Ingredients: Gelatin, Magnesium Stearate, Microcrystalline Cellulose, Maltodextrin

RESULTS

Significant ($p < 0.05$) group by time interactions were observed for diastolic blood pressure, creatinine, eGFR, chloride, CO2, globulin, A/G ratio, and HDL cholesterol. Dependent t tests revealed within-group differences between time points in SUP for diastolic blood pressure (+6.2 ± 5.3 mmHG , p = 0.008), creatinine (+0.09 ± 0.05 mg/dL, p = 0.001), eGFR (-11.2 ± 5.8 mL/min/1.73, p < 0.001), globulin (-0.29 ± 0.24 g/dL, p = 0.006), A/G ratio (+0.27 ± 0.23, p = 0.008), and HDL cholesterol (-5.0 ± 5.5 mg/dL, p = 0.027). In CRL, dependent t tests revealed intra-group differences for CO2 from pre to post supplementation (-1.9 ± 1.5 mmol/L, p = 0.001). For chloride, neither group reached significance ($p > 0.05$) for dependent t tests. Each of the aforementioned variables remained within accepted physiological reference ranges and were normally distributed ($p > 0.05$) at both time points. No other variables had significant group by time interactions. Data are presented as means ± SD in Table 1.

Table 1. Dependent variables collected pre and post supplementation

Variable	Group	Pre	Post	Δ	Reference Interval
Resting Systolic Blood Pressure (mmHg)	CRL	120.6 ± 12.3	121.4 ± 12.7	0.8 ± 6.9	< 120
	SUP	110.3 ± 11.9	116.8 ± 8.7	6.6 ± 6.5	
Resting Diastolic Blood Pressure (mmHg)	CRL	74.4 ± 8.9	74.1 ± 7.9	-0.3 ± 5.9	< 80
	SUP	70.7 ± 7.3	77.0 ± 5.0*	6.2 ± 5.3*	
Resting Heart Rate (b/min)	CRL	64.4 ± 10.2	65.2 ± 8.7	0.75 ± 5.8	< 100
	SUP	67.3 ± 9.5	71.4 ± 9.2	4.1 ± 12.7	
WBC (x10E3/uL)	CRL	5.84 ± 1.84	5.60 ± 1.72	-0.24 ± 0.69	3.4 - 10.8
	SUP	6.02 ± 1.09	6.00 ± 0.87	-0.07 ± 0.46	
RBC (x10E6/uL)	CRL	5.04 ± 0.34	5.03 ± 0.43	-0.01 ± 0.14	3.77 - 5.28
	SUP	5.24 ± 0.41	5.19 ± 0.40	-0.05 ± 0.17	
Hemoglobin (g/dL)	CRL	15.62 ± 1.11	15.54 ± 1.37	-0.08 ± 0.40	11.1 - 15.9
	SUP	15.46 ± 1.22	15.32 ± 1.06	-0.13 ± 0.62	
Hematocrit (%)	CRL	46.06 ± 3.14	45.46 ± 3.70	-0.59 ± 1.12	34.0 - 46.6
	SUP	45.67 ± 3.45	45.24 ± 3.45	-0.43 ± 1.86	
MCV (fL)	CRL	91.5 ± 2.6	90.4 ± 2.5	-0.9 ± 1.0	79 - 97
	SUP	88.9 ± 3.0	88.8 ± 3.7	-0.1 ± 1.8	
MCH (pg)	CRL	30.99 ± 0.71	30.90 ± 0.86	-0.09 ± 0.48	26.6 - 33.0
	SUP	29.57 ± 1.52	29.57 ± 1.28	0.00 ± 0.52	
MCHC (g/dL)	CRL	33.92 ± 0.75	34.18 ± 0.81	0.26 ± 0.67	31.5 - 35.7
	SUP	33.28 ± 0.82	33.32 ± 0.61	0.04 ± 0.82	
RDW (%)	CRL	13.42 ± 0.72	13.42 ± 0.60	0.00 ± 0.26	12.3 - 15.4
	SUP	13.44 ± 0.26	13.60 ± 0.39	0.16 ± 0.30	
Platelets (x10E3/uL)	CRL	280.4 ± 55.9	265.0 ± 51.5	-15.4 ± 15.7	150 - 379
	SUP	253.9 ± 73.1	241.6 ± 82.2	-12.1 ± 20.7	
Neutrophils (%)	CRL	55.2 ± 7.0	52.3 ± 6.8	-2.9 ± 5.3	40 - 74
	SUP	56.2 ± 7.0	52.1 ± 4.4	-3.9 ± 5.3	
Lymphocytes (%)	CRL	33.8 ± 5.5	35.2 ± 5.9	1.4 ± 3.1	14 - 46
	SUP	32.2 ± 6.8	35.0 ± 6.8	2.8 ± 3.6	
Monocytes (%)	CRL	9.2 ± 1.4	8.7 ± 1.8	-0.5 ± 1.7	4 - 12
	SUP	8.2 ± 1.9	8.6 ± 1.4	0.3 ± 2.7	
Eosinophils (%)	CRL	2.5 ± 1.6	2.9 ± 2.1	0.4 ± 0.9	0 - 5
	SUP	3.1 ± 2.1	3.6 ± 2.2	0.4 ± 1.4	
Basophils (%)	CRL	0.5 ± 0.9	0.6 ± 0.6	0.1 ± 0.8	0 - 3
	SUP	0.2 ± 0.4	0.6 ± 0.5	0.3 ± 0.5	
Neutrophils (Absolute) (x10E3/uL)	CRL	3.20 ± 1.28	3.05 ± 1.27	-0.15 ± 0.68	1.4 - 7.0
	SUP	3.38 ± 0.95	3.10 ± 0.95	-0.22 ± 0.28	
Lymphocytes (Absolute) (x10E3/uL)	CRL	1.96 ± 0.50	2.05 ± 0.55	0.09 ± 0.23	0.7 - 3.1
	SUP	1.94 ± 0.60	2.09 ± 0.70	0.15 ± 0.25	
Monocytes (Absolute) (x10E3/uL)	CRL	0.54 ± 0.14	0.47 ± 0.09	-0.08 ± 0.13	0.1 - 0.9
	SUP	0.51 ± 0.20	0.52 ± 0.15	0.01 ± 0.13	
Eosinophils (Absolute) (x10E3/uL)	CRL	0.15 ± 0.08	0.16 ± 0.09	0.01 ± 0.07	0.1 - 0.4
	SUP	0.19 ± 0.15	0.23 ± 0.17	0.04 ± 0.09	
Basophils (Absolute) (x10E3/uL)	CRL	0.03 ± 0.06	0.03 ± 0.04	-0.01 ± 0.04	0.0 - 0.2
	SUP	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	
Glucose (mg/dL)	CRL	82.6 ± 5.9	81.0 ± 13.0	-1.6 ± 11.0	65 - 99
	SUP	84.8 ± 2.8	86.0 ± 4.4	1.2 ± 3.1	
BUN (mg/dL)	CRL	14.7 ± 3.1	14.9 ± 3.4	0.2 ± 2.5	6 - 20
	SUP	16.7 ± 4.8	16.0 ± 4.5	-0.7 ± 2.5	
Creatinine (mg/dL)	CRL	0.98 ± 0.13	0.97 ± 0.15	-0.01 ± 0.06	0.57 - 1.27
	SUP	0.88 ± 0.17	0.97 ± 0.17*	0.09 ± 0.05*	
eGFR (mL/min/1.73)	CRL	93.8 ± 12.0	95.4 ± 16.0	1.6 ± 6.9	> 59
	SUP	104.2 ± 17.8	93.0 ± 14.9*	-11.2 ± 5.8*	
BUN/Creatinine Ratio	CRL	17.9 ± 5.1	17.1 ± 5.7	-0.7 ± 2.8	8 - 20
	SUP	19.1 ± 5.5	16.4 ± 5.0*	-2.7 ± 2.1	
Sodium (mmol/L)	CRL	136.5 ± 1.9	138.4 ± 2.5	0.3 ± 2.6	134 - 144
	SUP	137.2 ± 2.2	138.1 ± 1.5	0.9 ± 2.1	
Potassium (mmol/L)	CRL	4.06 ± 0.26	4.09 ± 0.24	0.03 ± 0.28	3.5 - 5.2
	SUP	4.09 ± 0.22	4.07 ± 0.22	-0.02 ± 0.17	
Chloride (mmol/L)	CRL	102.7 ± 2.0	102.3 ± 2.1	-0.4 ± 2.1	97 - 108
	SUP	100.8 ± 2.2	100.0 ± 1.9*	-0.8 ± 1.5	
Carbon Dioxide (mmol/L)	CRL	22.1 ± 1.9	20.2 ± 2.0	-1.9 ± 1.5	18 - 28
	SUP	21.2 ± 2.8	22.7 ± 2.4*	1.4 ± 2.6*	
Calcium (mg/dL)	CRL	9.29 ± 0.29	9.27 ± 0.38	-0.02 ± 0.29	8.7 - 10.2
	SUP	9.38 ± 0.32	9.54 ± 0.31	0.17 ± 0.29	
Protein (g/dL)	CRL	7.05 ± 0.26	6.99 ± 0.34	-0.06 ± 0.22	6.0 - 8.5
	SUP	7.04 ± 0.31	6.88 ± 0.38	-0.17 ± 0.24	
Albumin (g/dL)	CRL	4.42 ± 0.18	4.39 ± 0.22	-0.03 ± 0.17	3.5 - 5.5
	SUP	4.39 ± 0.19	4.51 ± 0.35	0.12 ± 0.26	
Globulin (g/dL)	CRL	2.63 ± 0.24	2.60 ± 0.26	-0.03 ± 0.11	2.3 - 4.5
	SUP	2.68 ± 0.26	2.37 ± 0.22*	-0.29 ± 0.24*	
A/G Ratio	CRL	1.71 ± 0.21	1.74 ± 0.28	0.03 ± 0.11	1.1 - 2.5
	SUP	1.67 ± 0.17	1.93 ± 0.21*	0.27 ± 0.23*	
Bilirubin (mg/dL)	CRL	0.54 ± 0.21	0.49 ± 0.22	-0.05 ± 0.21	0.0 - 1.2
	SUP	0.54 ± 0.26	0.44 ± 0.20	-0.10 ± 0.13	
Alkaline Phosphatase (IU/L)	CRL	65.4 ± 29.5	64.9 ± 27.7	-0.4 ± 4.5	39 - 117
	SUP	70.0 ± 23.0	67.4 ± 20.8	-2.6 ± 5.5	
AST (IU/L)	CRL	26.3 ± 8.5	25.4 ± 6.9	-0.9 ± 5.8	0 - 40
	SUP	22.7 ± 6.7	24.0 ± 8.6	1.3 ± 5.5	
ALT (IU/L)	CRL	26.9 ± 10.5	25.1 ± 8.2	-1.7 ± 5.0	0 - 32
	SUP	20.7 ± 7.6	22.4 ± 9.8	1.8 ± 5.2	
Total Cholesterol (mg/dL)	CRL	184.9 ± 28.1	187.5 ± 29.8	2.6 ± 13.9	100 - 199
	SUP	168.7 ± 16.4	169.3 ± 12.3	0.5 ± 18.3	
Triglycerides (mg/dL)	CRL	79.6 ± 33.6	91.6 ± 55.8	12.0 ± 56.5	0 - 114
	SUP	90.7 ± 27.4	98.3 ± 38.0	8.2 ± 36.8	
HDL (mg/dL)	CRL	61.3 ± 13.1	63.0 ± 11.5	1.7 ± 3.8	> 39
	SUP	60.0 ± 12.2	55.0 ± 11.8*	-5.0 ± 5.5*	
LDL (mg/dL)	CRL	82.6 ± 28.4	86.1 ± 20.5	3.4 ± 16.8	0 - 129
	SUP	90.7 ± 11.5	84.6 ± 7.3	-6.1 ± 15.2	

CRL = Control (n=14); SUP = Supplement (n=9); All data are reported as means ± SD.

† Significantly different than corresponding CRL delta, t-test ($p < 0.05$)

*Significantly different from CRL ($p < 0.05$)

CONCLUSIONS

The present study confirms the hypothesis that chronic daily consumption of a multi-ingredient TRM will not cause adverse changes in hematological markers of clinical safety or resting vital signs in healthy adults. Although there were statistically significant ($p < 0.05$) group by time interactions for diastolic blood pressure, creatinine, eGFR, chloride, CO2, globulin, albumin:globulin ratio, and HDL cholesterol, all of the results remained well within accepted physiological ranges and were not clinically significant. In sum, it appears as though daily supplementation with up to 2 servings of a TRM has no adverse effects on markers of clinical safety among healthy adults for a period of 28 days.

PRACTICAL APPLICATIONS

For healthy individuals or athletes considering supplementation to possibly help reduce body fat or mass, the multi-ingredient TRM in the present study appears to be safe for chronic daily consumption.

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ACKNOWLEDGEMENTS

This study was funded by MusclePharm, Inc. (Denver, CO).