Study #5 Weight Loss Effect in Overweight Women Clinical Study

Purpose

Consuming Celsius prior to exercising improves body composition and lipid profile (cholesterol, triglyceride levels) in overweight and obese women.

Results

Overweight and obese women drinking Celsius prior to moderate exercise resulted in increased fat loss, increased muscle mass, increased endurance performance with significant improvements to blood lipid profiles when compared to exercise alone.

Participants' results included:
46% greater fat loss
27% greater muscle mass
35% greater endurance performance.

Drinking Celsius with or without exercise showed a significant drop in total cholesterol (5 to 13%) and bad LDL cholesterol (12-18%). Exercise alone had no impact on blood lipid levels.

University of Oklahoma 2009

LOW-CALORIE THERMOGENIC BEVERAGE AND EXERCISE IMPROVES BODY COMPOSITION AND LIPID PROFILE IN OVERWEIGHT AND OBESE WOMEN

Abbie E. Smith, Jordan R. Moon, Christopher M. Lockwood, Kristina L. Kendall, Jennifer L. Graef, David H. Fukuda, Joel T. Cramer**,** Jeffrey R. Stout. Department of Health and Exercise Science, University Of Oklahoma, Norman, OK

The purpose of this study was to evaluate the combined effects of a 10-week exercise program with chronic ingestion of a thermogenic energy drink on body composition, cardiovascular fitness, strength, and safety in overweight and obese women. In a double-blind placebo-controlled approach overweight and obese women (n=27) were randomly assigned to groups that consumed identically tasting treatment beverages with exercise (EX-Act: n=6; EX-PL: n=9) or without exercise (NEX-Act: n=7; NEX-PL: n=5). All participants consumed one drink per day for 10 weeks; EX-Act and EX-PL participated in a 10-week endurance and resistance training program. Fifteen minutes prior to each workout, participants consumed their assigned drink; on non-training days the same beverage was consumed *ad libitum*. Changes in body composition were assessed using a four-compartment model. Changes in muscle mass (MM) were evaluated using a previously published equation based on DXA-derived appendicular lean-soft tissue. Cardiovascular fitness and upper- and lower-body strength were assessed prior to and following the 10-week intervention. Separate two-way repeated measures ANOVAs [treatment (EX-Act vs. EX-PL vs. NEX-Act vs. NEX-PL) x time (Pre vs. Post)] indicated a significant time x treatment interaction for muscle mass ($p=0.026$) and total cholesterol ($p=0.047$); a significant time x training interaction for VO_2peak ($p=0.046$), ventilatory threshold (VT, $p=0.014$), upper- and lower-body strength ($p<0.05$). Post hoc analyses revealed a significant difference between the EX- and NEX-groups for percent change in muscle mass (EX-Act: 6.8 ± 2.5%; EX-PL: 5.1 ± 2.4%; NEX-Act: 1.1 ± 3.2%; NEX-PL: 1.4 ± 1.3%) and VO_2peak (EX-Act: 13.4 ± 10.1%; EX-PL: 8.9 ± 6.9%; NEX-Act: 2.1 ± 6.6%; NEX-PL: 7.2 ± 5.4%), VT (EX-Act: 46.2 ± 23.3%; EX-PL: 15.0 ± 15.6%; NEX-Act: 6.6 ± 17.5%; NEX-PL: 10.3 ± 22.4%), upper- (EX-Act: 14.4 ± 10.1%; EX-PL: 20.9 ± 8.3%; NEX-Act: 2.0 ± 3.4%; NEX-PL: 2.7 ± 7.7%) and lower- (EX-Act: 33.3 ± 23.9%; EX-PL: 31.7 ± 23.94%; NEX-Act: 1.4 ± 4.1%; NEX-PL: 1.2 ± 3.0%) body strength. Clinical markers for hepatic and renal function revealed no adverse effects in response to the beverage consumption. Total cholesterol significantly decreased for the Act supplementing groups (EX-Act: -5.0 ± 4.7%; NEX-Act: -10.7 ± 15.4% vs. EX-PL: +3.0 ± 12.8%, NEX-PL: +0.3 ± 8.9%). The current data suggest that the ACSM exercise program guidelines provide an effective measure for improving cardiovascular fitness, strength and modifying body composition. Individual data demonstrate support for implementing a single serving thermogenic drink prior to exercise, to improve muscle mass, decrease fat mass and improve lipid profiles of overweight women, compared to exercise alone.

Abstract 63

THE EFFECT OF PLATE SIZE ON ENERGY INTAKE IN NORMAL AND OVERWEIGHT/OBESE SUBJECTS

Schroeder B[a], Winn W[a], **Shah M[a,b]**, Adams-Huet B[b]. [a]Dept. of Kinesiology, TCU, Fort Worth, TX & [b]Dept. of Clinical Sciences, UT Southwestern Medical Center, Dallas, TX.

Only one study has examined the role of plate size on energy intake and there is no data on the effect by weight status. This study determined if plate size affects energy intake and whether overweight/obese (OW) subjects (BMI ≥ 25 kg/m²) respond to plate size differently compared with normal weight (NW) subjects (BMI: 18.5-24.9 kg/m²).

Ten NW and 10 OW women were recruited for the study. Each subject came to the metabolic lab on two different days, separated by at least 2 days, for lunch. During the first day, each subject was randomly assigned to eat using either a small plate (SP) (8.5") or large plate (LP) (10.75") and was asked to serve herself as much spaghetti with red sauce as she wanted from her own individual serving bowl onto her plate. During the second day, the subject underwent the same procedure but with the different size plate. The amount of food consumed during each occasion was determined by weighing the serving bowl and plate before and after the food was consumed. The data were analyzed using a 2 factor [plate size (repeated factor) and weight status] ANOVA.

There was no effect (mean±SD) of plate size x weight status (NW-LP: 326±94 kcal; NW-SP: 324±123 kcal; OW-LP: 293±103 kcal; OW-SP: 314±151 kcal; p=0.55), plate size (LP: 309±98 kcal; SP: 319±134 kcal; p=0.60), or weight status (NW: 325 kcal; OW: 303 kcal; p=0.67) on energy intake. Plate size did not affect energy intake and the response was not different in NW and OW subjects.

Abstract 64

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Abstract 65

FOLLOW UP INVESTIGATION OF EARLIER OBESE SCHOOLCHILDREN WITH INSULIN RESISTANCE TREATED BY LIFESTYLE MODIFICATION

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Long time effect of lifestyle modification (LM) advised against insulin resistance syndrome (IRS) is not established, therefore repeated investigation of our earlier patients were performed after ten years. Our invitation was accepted by 127 patients whose IRS was thought to be improved after a 2 years long care 8 years ago. 28 have continued (group 1), 42 have partly continued (group 2), 57 have not continued (group 3) the LM. BMI, BP, carbohydrate and lipid metabolic parameters were determined. BMI was > 25 together with high SBP in 4, 6, 31 cases from group 1, 2, 3, respectively. The frequency difference between group 1 and 3 was significant. Impaired glucose tolerance together with hyperinsulinemia were found in 9, 13, 39 cases from group 1, 2, 3, respectively w/o significant frequency differences. No pathologic serum lipid parameters were observed. The effect of LM on different IRS risk factors seems to be due to the compliance time and the factor,s nature.

Abstract 66

SIGNIFICANT IMPROVEMENTS IN VIGOR, MOOD STATE AND HORMONE PROFILE ASSOCIATED WITH LIFESTYLE

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Chronic stress plays a major role in the pathophysiology of many disease states, particularly psychological disorders including depression, chronic fatigue, anxiety, fibromyalgia, and burnout. These stress-related changes in psychology may be due to both endocrine and behavioral factors – and may be mediated or attenuated by lifestyle factors including diet and exercise.

Vigor is defined as a 3-tiered sustained mood-state that is characterized by (1) physical energy, (2) mental energy, and (3) cognitive liveliness. Vigor can also be described as the opposite of "Burnout" (physical fatigue, mental exhaustion, cognitive weariness).

Our objective was to assess changes in Vigor, Mood State, and Hormone Profile in response to a lifestyle intervention. We recruited 117 moderately stressed subjects (95 women / 22 men) in three cohorts at different times of the year (January, May, November). Subjects followed a 6-12 week regimen (depending on cohort) including a balanced diet, moderate exercise (3-5 d/wk), and an herbal dietary supplement based on *Eurycoma longifolia* (a Malaysian traditional remedy for improving mood and energy levels). We measured endocrine parameters (salivary cortisol to testosterone (C:T) ratio), and Global Mood State (MOOD) and related subscales: Vigor (V), Fatigue (F), and Depression (D), using the Profile of Mood States (POMS) psychological survey before and after the intervention. Significant changes (all, p<0.05) were found for C:T (-15-19%), MOOD (+20-22%), V (+27-29%), F (-41-48%), and D (-40-52%). These data indicate that factors that are typically disrupted during chronic stress (hormone profile and psychological mood state) may be positively and significantly

Low-calorie Thermogenic Beverage and Exercise Improves Composition and Lipid Profile in Overweight and Obese Women

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Abstract

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Acknowledgements : This study was funded by Celsius®, Inc., Delray Beach, FL

INTRODUCTION

Weight loss supplements are widely available and superfluously marketed, while lacking substantial efficacy and safety data. Many supplements are marketed as 'natural' and therefore relaying 'safety' again lacking supporting data. Furthermore, many weight loss supplements fail to recognize the combination of diet and exercise, as the effective way to losing weight. Many common 'natural' ingredients, such as caffeine, green tea, and ginseng, have made their way into weight loss supplements, as effective thermogenic and lipolytic ingredients. Specifically, it has previously been reported (1) that a commercially available, low-calorie thermogenic drink (Celsius®, Celsius, Inc., Delray Beach, FL) significantly increased resting energy expenditure (REE) and serum free fatty acids (FFA) in response to acute oral ingestion compared to a placebo. In addition, Roberts et al. (2) reported a decrease in percent body fat (%FAT), increased serum FFA and no significant differences in blood lipids or other metabolic safety indices after 28 days of chronic ingestion of the same energy drink versus placebo. Dalbo et al. (1) found that compared to placebo, Celsius® significantly increased REE (kcal/d) by approximately 10% after 120 minutes post-ingestion, with no change seen at 180 minutes. At 30, 60, 120 and 180 minutes post-ingestion, circulating FFA concentrations were also significantly elevated, compared to placebo. Concluding that this thermogenic drink may be an effective stimulus to promote weight loss and changes in body composition, independent of modifications in diet or exercise (1). Moreso, Lockwood et al. (3) demonstrated that when combined with exercise, consuming a thermogenic drink prior to exercise may safely improve body composition and strength and fitness in healthy men Therefore, the purpose of this study was to evaluate the combined effects of a 10-week exercise program with chronic ingestion of a thermogenic energy drink on body composition, cardiovascular fitness, strength, and safety in overweight and obese women.

EXPERIMENTAL DESIGN

This study implemented a randomized, double-blind placebo-controlled design examining the combined effects of a 10-week pre-exercise intervention with a low-calorie energy and thermogenic beverage (Celsius®, Celsius, Inc. Delray Beach, FL) and five days per week of combined aerobic and resistance exercise. Participants were randomized into one of four groups: active energy drink + exercise (EX-Act), energy drink only (NEX-Act), placebo + exercise (EX-PL) or placebo only (NEX-PL), and consumed their respective drink one time per day, either alone or in combination with exercise. Participants consumed their respective drink *ad libitum* on the other two days per week. Body composition was assessed using a four-compartment model (4) at Baseline and after 12 weeks of exercise and supplementation. Cardiovascular and strength testing were conducted within 24 hours of baseline and post-testing, and blood safety measures were also assessed after a 12-h fast.

METHODS

GROUP	Age (yrs)	Height (cm)	Body Mass (kg)	% BF (%)
EX-Act				
n=6	31.17 ± 8.23	164.22 ± 11.10	78.60 ± 9.54	39.59 ± 2.78
EX-PL				
n=9	23.56 ± 7.42	163.37 ± 4.64	73.06 ± 10.40	38.49 ± 3.40
NEX-Act				
n=7	27.86 ± 9.21	163.47 ± 4.31	68.62 ± 12.90	37.56 ± 2.56
NEX-PL				
n=5	28.40 ± 10.16	169.26 ± 13.12	79.25 ± 11.68	36.22 ± 1.52
N=27	27.26 ± 8.60	164.67 ± 8.13	74.29 ± 11.33	38.07 ± 2.87

BODY COMPOSITION (4C-MODEL)

All body composition measurements were performed on the same day following a 12-hour fast (water intake was allowed up to one hour prior to testing). Hydration status was determined prior to all testing using specific gravity via handheld refractometry (Model CLX-1, precision = 0.001 ± 0.001, VEE GEE Scientific, Inc., Kirkland, WA) to assure proper hydration from PRE (1.022 ± 0.007) to POST (1.021 ± 0.007) measurements. Fat mass (FM), percent body fat (%FAT) and fat-free mass (FFM) were estimated using the four-compartment (4-C) model described by Wang et al.(4)

FM (kg) = 2.748(BV)-0.699(TBW) + 1.129(Mo)- 2.051(BM)

%FAT = (FM/BM) x 100

FFM (kg) = BM-FM

Where BV is total body volume, TBW is total body water, MO is total body bone mineral, and BM is body mass.

Dual-energy X-ray absorptiometry (DXA) (software version 10.50.086, Lunar Prodigy Advanced, Madison, WI) was used to estimate total bone mineral content and total body muscle mass (MM). Bone mineral content (BMC) was converted to Mo using the following equation: Mo = total body BMC x 1.0436. In addition, the sum of lean soft tissue for both arms and legs (ALST), as measured by CXA, was used to estimate MM from the validated equation of Kim et al.(5). MM = (1.13 x ALST) - (0.02 x age) + [0.61 x sex (m = 0, f = 1)] + 0.97.

Body volume (BD) was assessed from HW with correction for residual volume (RV). Residual volume was determined with the subject in a seated position using the oxygen dilution method of Wilmore (6) via a metabolic cart with residual volume software (True One 2400®, Parvo-Medics, Inc. Provo, UT.). Underwater weight was measured to the nearest 0.025kg in a submersion tank in which a PVC swing seat was suspended from a calibrated Chatillon® 15-kg scale (Model # 1315DD-H, Largo, FL.). Previous test retest measurements of eleven men and women measured 24-48 hours apart for HW produced a SEM of 0.

A deuterium oxide (D_2O) tracer was used as the criterion method to estimate TBW. Prior to D2O ingestion, urine samples were collected from all subjects. After voiding the bladder completely, subjects ingested ≈ 11 grams of D2O along with a 100 ml rinse of deionized water. After a four hour equilibration period restricting defecation, urination and food and water ingestions, subjects were instructed to provide a post-urine sample. Within 30 minutes of collection, all urine samples were pipette into cryogenic vials and stored at -80˚C for later analysis . All urine-diluted samples were measured in triplicate at an independent laboratory (Metabolic Solutions, Inc., Nashua, NH) using an isotope-ratio mass spectrometer, and the isotope abundances in the urine were calculated as previously reported by Wong et al. (7) TBW was then calculated from the dilution of isotopic water and corrected for the exchange of deuterium with non-aqueous tissue (7). Reliability measurements from 11 men and women for D2O in one urine sample measured in triplicate resulted in a SEM value of 0.33L.

BODY COMPOSITION CALCULATION

Body fat was estimated using the four-compartment model (4C) of Wang et al. (4) using the following equation:

FM (kg) = 2.748(BV)-0.699(TBW) + 1.129(Mo)- 2.051(BM)

%FAT = (FM/BM) x 100

FFM (kg) = BM-FM

Where BV is total body volume, TBW is total body water, MO is total body bone mineral, and BM is body mass.

CARDIOVASCULAR TESTING

Described by Rossiter et al. (8), using a Corival 906900 (Lode B.V. Medical Technology, Groningen, The Netherlands) upright cycle ergometer participants were instructed to pedal at a cadence of 60-80 RPMs, with resistance beginning at 20 Watts (W) and increasing in 20W/min (1W/3sec) until volitional fatigue or until participants could no longer maintain >50 RPMs, despite strong verbal encouragement. Respiratory gases were monitored and continuously analyzed with open-circuit spirometry to calculate minute ventilation (V_E), oxygen consumption rate (VO_2), carbon dioxide expiration rate (VCO_2), ventilatory threshold (VT) and respiratory exchange ratio (RER) using a metabolic cart and manufacturer's software (True One 2400®, Parvo-Medics, Inc., Provo, UT). The data were averaged over 15-second intervals, with the highest 15-second VO_2 value recorded as the peak oxygen uptake (VO_2peak). Prior to testing, flow rate, O_2 and CO_2 analyzers were calibrated following the manufacturer's recommendations.

EXERCISE PROTOCOL

The exercise program was designed using the American College of Sports Medicine (ACSM) recommended guidelines for apparently healthy adults; all participants

were supervised by a certified trainer. Progressive endurance training, on cycle ergometers, was performed three days per week (Table 2). Resistance training was performed two days per week, providing at least 24 hours recovery between sessions. Participants completed nine isotonic exercises incorporating both single-joint and multi-joint exercises. Each exercise was performed once per session, with participants completing 8-12 repetitions per exercise, until volitional fatigue. Weight was increased when participants performed >10 repetitions, at the same resistance, during two consecutive lifting sessions.

Table 2

Week	**Duration (min)**	**%HRR**
1	15 – 20	40 – 50
2	20 -25	40 – 50
3	25 – 30	50 -60
4	25 – 30	50 -60
5	25 – 30	60 – 70
6	25 – 30	60 – 70
7	25 – 30	60 – 70
8	30 – 35	60 – 70
9	30 – 35	60 – 70
10	30 – 35	60 – 70

HRR = Heart rate reserve

THERMOGENIC DRINK PROTOCOL

All participants were instructed to consume one drink per day, for a total of 70 consecutive days (10 weeks). During exercise days, participants reported to the training facility and consumed one drink prior to exercise; initiating exercise 15 minutes after consumption. On non-exercise days, time of day for consuming the beverage was left to the subject's discretion. Figure 1 provides the supplement facts panel for the beverage (Celsius®, Celsius Inc., Delray Beach, FL) consumed by participants in CEX. Participants in PLX consumed an identically canned and labeled placebo beverage that yielded an identical supplement facts profile, minus the "Celsius® Thermogenic Blend" (taurine, guarana seed extract, green tea leaf extract standardized to 10% EGCG, caffeine as caffeine anhydrous, glucuronolactone and ginger root extract).

Supplement Facts

Serving Size 12 fl. oz
Servings per Container 1

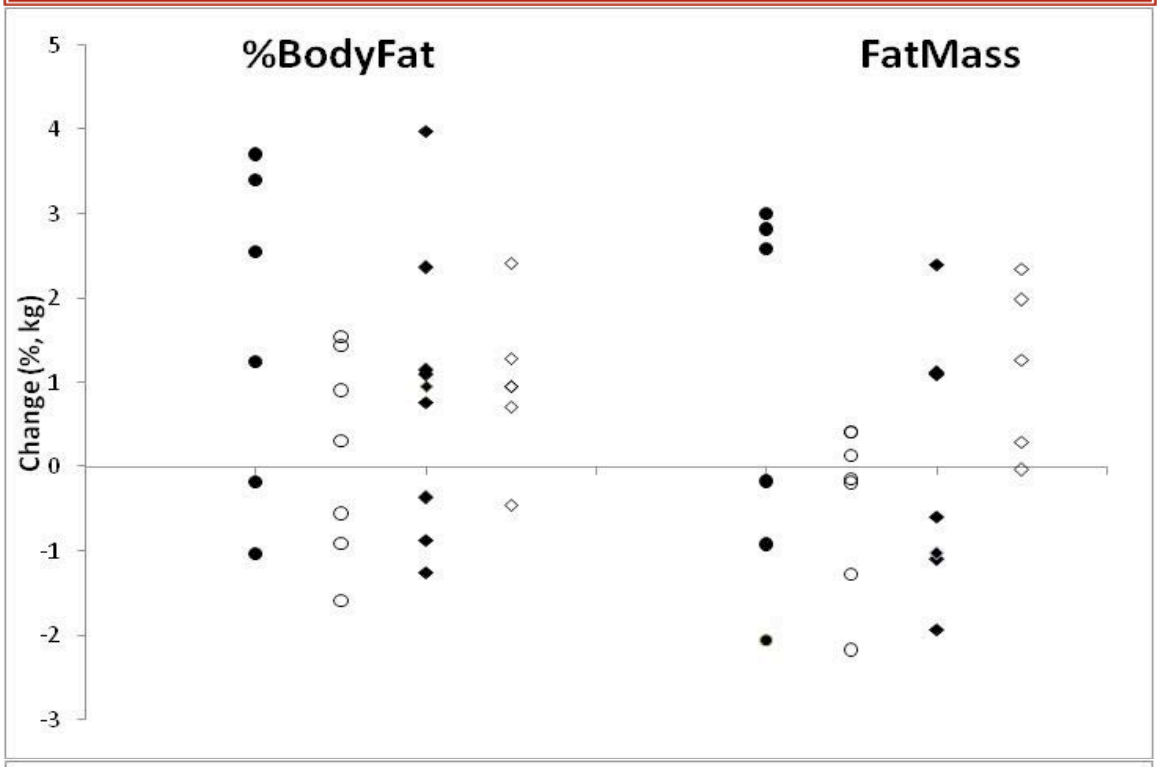
Amount per serving		%DV†
Calories	10	
Total Carbohydrates	1g	<1%
Sugar	0g	
Vitamin C (ascorbic acid)	60mg	100%
Riboflavin	1.7mg	100%
Niacin (as niacinamide)	20mg	100%
Vitamin B6 (as pyridoxine hydrochloride)	2mg	100%
Vitamin B12 (as cyanocobalamin)	6mcg	100%
Biotin	300mcg	100%
Pantothenic Acid (as calcium d-pantothenate)	10mg	100%
Calcium (as calcium carbonate)	50mg	5%
Chromium (chelate)	50mcg	41%
Sodium	6mg	<1%
MetaPlus™	1,810mg	
Taurine		**
Guarana extract (seed)		**
Green Tea leaf extract (leaf) standardized to 10% EGCG		**
Caffeine (as caffeine anhydrous)		**
Glucuronolactone		**
Ginger extract (root)		**

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

Other Ingredients: Filtered Water, Natural Colors, Natural Flavors, Citric Acid, Sucralose
Contains: 200 mg total caffeine per serving

Not recommended for people that are caffeine sensitive, children under 12, or women pregnant or nursing.

RESULTS


%BodyFat
FatMass
Change (%, kg)
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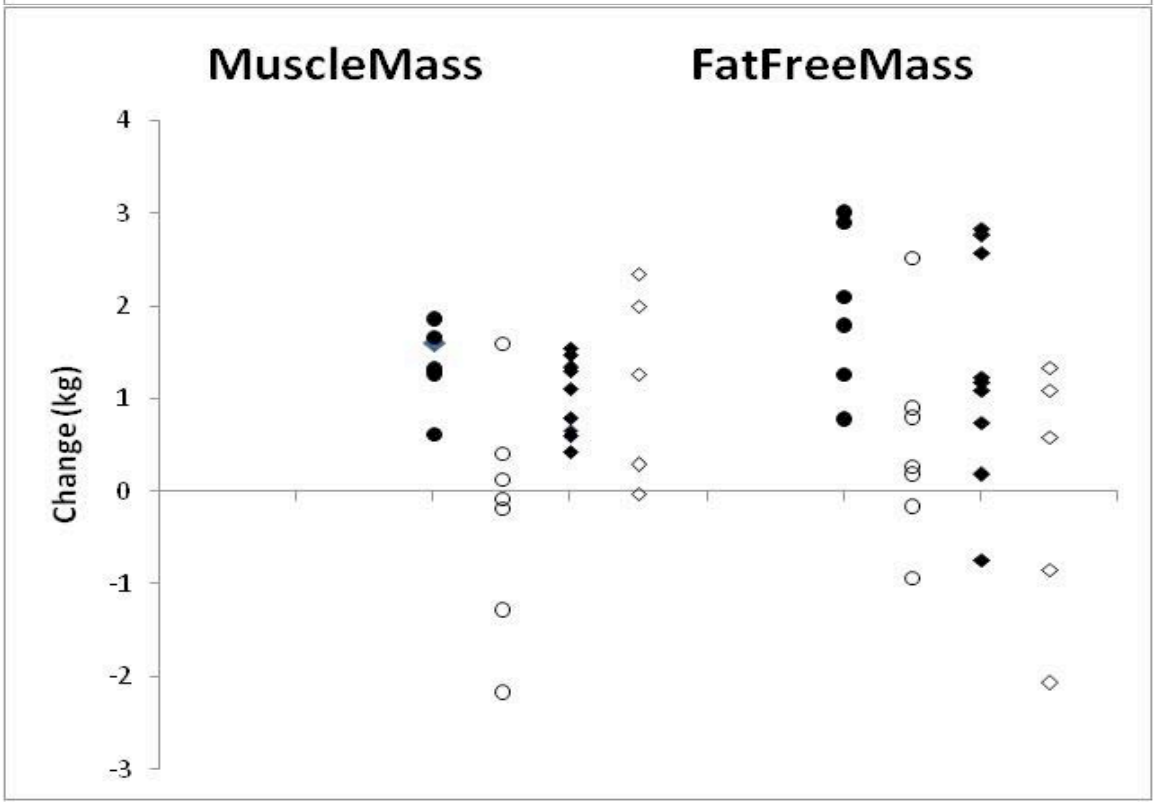
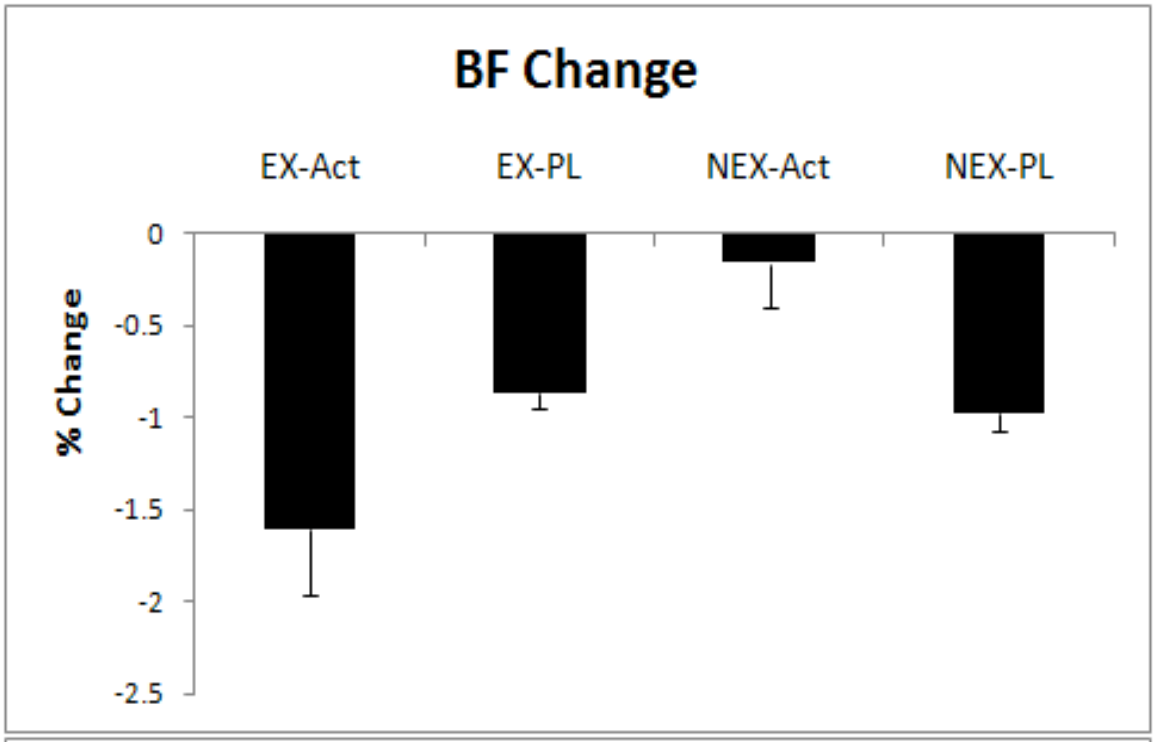
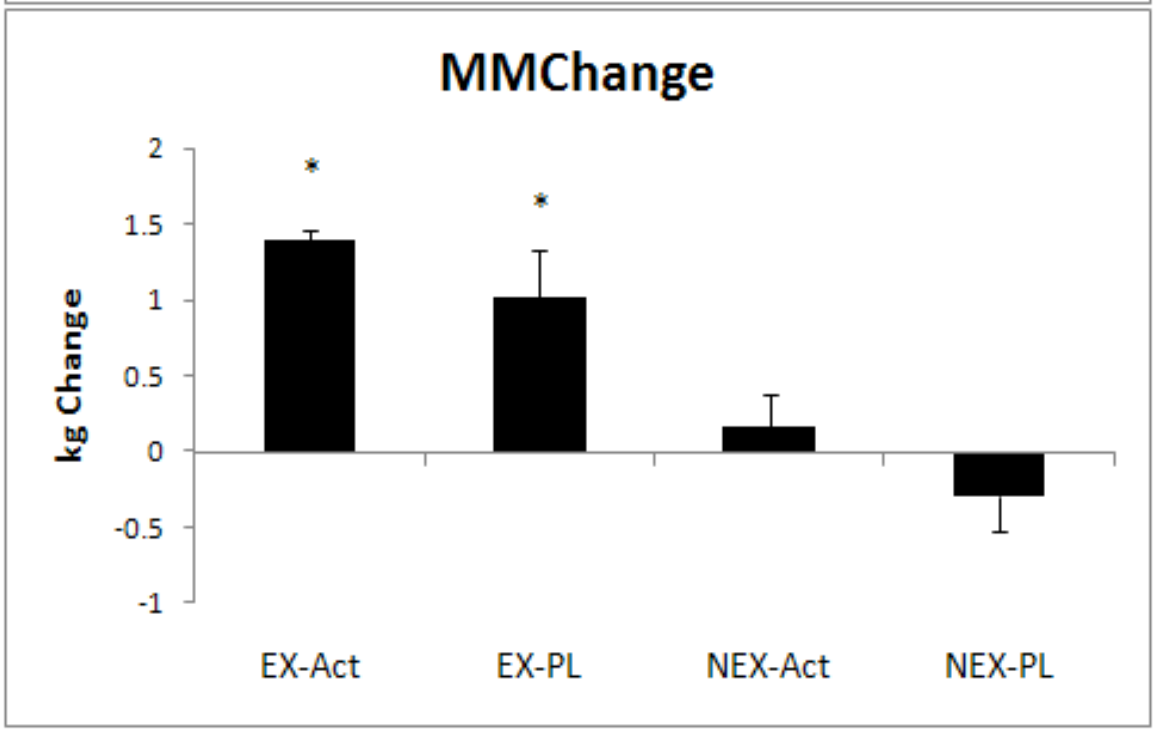
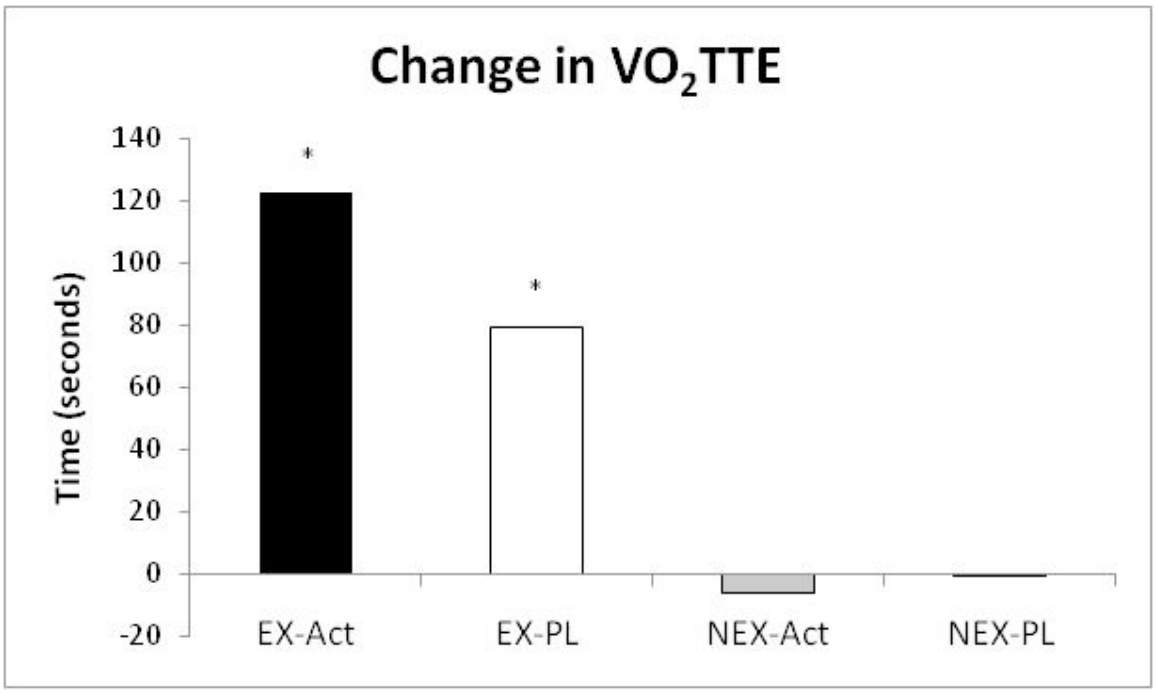
3
2
1
0
-1
-2
-3


MuscleMass
FatFreeMass
Change (kg)
4
3
2
1
0
-1
-2
-3





Using a two-way repeated measures ANOVA, significant time*treatment interactions resulted for muscle mass ($p<0.05$). 100% of the subjects in the Act supplementing group increased Muscle mass, while 45% of the EX-PL group and 20% of the individuals in the NEX-PL group increased in muscle mass. Although the decrease in %BF was not significant, 50% of the Ex-Act group saw a decrease (MD 1.8%), 22% in the Ex-PL, 20% in the NEX-PL and no one in the NEX-Act.


Change in VO2TTE
Time (seconds)
140
120
100
80
60
40
20
0
-20
*
*
EX-Act
EX-PL
NEX-Act
NEX-PL

Changes in fasting lipid concentrations from PRE to POST				
Total Cholesterol (mg/dL)			PRE	POST
		EX-Act	211.33 ± 30.22	200.33 ± 27.37*
		EX-PL	161.67 ± 26.50	165.56 ± 26.69
		NEX-Act	199.57 ± 65.38	173.14 ± 41.59
		NEX-PL	170.40 ± 31.61	170.20 ± 31.23
HDL (mg/dL)				
		EX-Act	52.33 ± 9.04	52.83 ± 7.17
		EX-PL	54.11 ± 8.96	54.89 ± 10.45
		NEX-Act	55.29 ± 6.97	51.86 ± 8.40
		NEX-PL	51.80 ± 15.83	57.20 ± 20.56
LDL (mg/dL)				
		EX-Act	137.50 ± 30.85	120.33 ± 24.31*
		EX-PL	92.56 ± 22.69	93.00 ± 19.67
		NEX-Act	125.57 ± 61.15	102.43 ± 37.48*
		NEX-PL	101.20 ± 30.04	95.40 ± 31.00
VLDL (mg/dL)				
		EX-Act	21.50 ± 5.13	27.17 ± 7.25
		EX-PL	15.00 ± 5.20	17.67 ± 4.64
		NEX-Act	18.71 ± 6.26	18.86 ± 7.80
		NEX-PL	17.40 ± 5.68	17.60 ± 7.20
Triglycerides (mg/dL)				
		EX-Act	108.00 ± 24.80	135.83 ± 35.49*
		EX-PL	74.44 ± 26.17	87.67 ± 22.27
		NEX-Act	94.14 ± 31.21	95.14 ± 38.19
		NEX-PL	86.40 ± 29.10	88.20 ± 35.07

Strength and cardiovascular improvements were significantly ($p<0.05$) augmented in both training groups. However, a significant time*treatment interaction resulted for time to exhaustion during the VO2peak ($p=0.046$)

Safety data suggest this thermogenic drink as an effective method for lowering TC and LDL (main effect for treatment).

CONCLUSIONS

The current data suggest that the ACSM exercise program guidelines provide an effective measure for improving cardiovascular fitness, strength and modifying body composition. Individual data demonstrate support for implementing a single serving thermogenic drink prior to exercise, to improve muscle mass, decrease fat mass and improve lipid profiles of overweight women, compared to exercise alone. Additionally, our data suggest that consuming a single serving of Celsius® prior to working out may enhance the positive adaptations of chronic exercise on body composition and cardiorespiratory fitness and endurance performance in previously sedentary overweight women.

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