

# **Safety and Efficacy of Energize™ Administration in Healthy Men and Women**

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## **ABSTRACT**

**Objective:** The purpose of this clinical trial was to determine the safety and efficacy of acute Energize™ supplementation in healthy men and women.

**Methods:** After giving informed consent and being cleared for participation by passing a screening physical, ten healthy men and women aged 25-50 yr began a randomized, placebo-controlled, crossover trial. All subjects completed two trials using a counterbalanced design. Metabolic rate (via indirect calorimetry) and substrate oxidation (via respiratory exchange ratios) were measured at baseline (pre-ingestion) and for 10 minutes at the end of each hour for 2 hours post-ingestion. Resting heart rate and blood pressure were measured at 0, 30, 60, 90, and 120 minutes post-ingestion. Profile of Mood States (POMS) were also measured pre and 120 minutes post-ingestion.

**Results:** Two-way ANOVA revealed a significant interaction ( $p \leq 0.0001$ ) for resting metabolic rate between conditions. Specifically, ingestion of Energize™ caused a statistically significant increase in metabolic rate at 60 min (11%;  $P < 0.0002$ ) and 120 min (14%;  $P < 0.0001$ ) compared to the placebo trial. No statistical differences were noted in blood chemistries or cardiovascular measurements from pre to post testing.

**Conclusions:** These preliminary findings indicate that a single dose of Energize™ has thermogenic properties when ingested acutely and raises resting metabolic rate 13.5% above baseline for at least 2 hours post-ingestion.

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## Energize Group

	<b>Valid N</b>	<b>Mean</b>	<b>Minimum</b>	<b>Maximum</b>	<b>Std.Dev.</b>
<b>Age</b>	10	36.0000	28.0000	44.0000	5.03322
<b>Hgt</b>	10	174.4000	165.0000	183.0000	6.22183
<b>Wgt</b>	10	74.9100	58.2000	118.2000	18.64388
<b>RMR 0</b>	10	3.9220	3.1700	4.3600	0.31885
<b>RMR 60</b>	10	4.3460	4.0900	4.7500	0.21634
<b>RMR 120</b>	10	4.4580	3.9700	4.9500	0.33179
<b>HR 0</b>	10	64.6000	52.0000	78.0000	8.07190
<b>HR 30</b>	10	63.4000	51.0000	82.0000	10.50079
<b>HR 60</b>	10	62.5000	47.0000	81.0000	11.20764
<b>HR 90</b>	10	61.8000	49.0000	80.0000	10.20675
<b>HR 120</b>	10	62.7000	48.0000	78.0000	9.51081
<b>SBP 0</b>	10	115.8000	95.0000	138.0000	12.07201
<b>SBP 30</b>	10	121.0000	111.0000	142.0000	9.40449
<b>SBP 60</b>	10	123.6000	110.0000	144.0000	11.29602
<b>SBP 90</b>	10	122.6000	112.0000	144.0000	10.12368
<b>SBP 120</b>	10	124.9000	109.0000	142.0000	10.43977
<b>DBP 0</b>	10	75.7000	64.0000	90.0000	7.60190
<b>DBP 30</b>	10	77.9000	69.0000	92.0000	7.01506
<b>DBP 60</b>	10	76.0000	51.0000	94.0000	11.64283
<b>DBP 90</b>	10	77.8000	72.0000	94.0000	7.13053
<b>DBP 120</b>	10	80.4000	70.0000	92.0000	6.44981

Independent t-tests revealed no difference for any pre-value!

Placebo Group

	Valid N	Mean	Minimum	Maximum	Std.Dev.
<b>Age</b>	10	36.0000	28.0000	44.0000	5.03322
<b>Hgt</b>	10	174.4000	165.0000	183.0000	6.22183
<b>Wgt</b>	10	74.9100	58.2000	118.2000	18.64388
<b>RMR 0</b>	10	4.0260	3.4500	4.8600	0.37577
<b>RMR 60</b>	10	4.0540	3.4600	4.7400	0.33504
<b>RMR 120</b>	10	4.0180	3.4300	4.7600	0.37034
<b>HR 0</b>	10	64.4000	53.0000	78.0000	7.53068
<b>HR 30</b>	10	61.4000	51.0000	78.0000	9.28799
<b>HR 60</b>	10	63.9000	53.0000	84.0000	10.53513
<b>HR 90</b>	10	63.6000	50.0000	80.0000	10.30857
<b>HR 120</b>	10	62.1000	49.0000	78.0000	10.10445
<b>SBP 0</b>	10	118.7000	106.0000	138.0000	10.94481
<b>SBP 30</b>	10	119.2000	105.0000	138.0000	10.76827
<b>SBP 60</b>	10	120.3000	104.0000	140.0000	11.23536
<b>SBP 90</b>	10	118.1000	104.0000	136.0000	10.57723
<b>SBP 120</b>	10	120.7000	104.0000	140.0000	10.77085
<b>DBP 0</b>	10	70.2000	4.0000	90.0000	24.30729
<b>DBP 30</b>	10	75.3000	62.0000	90.0000	8.99444
<b>DBP 60</b>	10	75.6000	64.0000	92.0000	8.73308
<b>DBP 90</b>	10	73.8000	50.0000	92.0000	12.04436
<b>DBP 120</b>	10	73.1000	49.0000	90.0000	11.75160

Dependent t-test for Energize Group

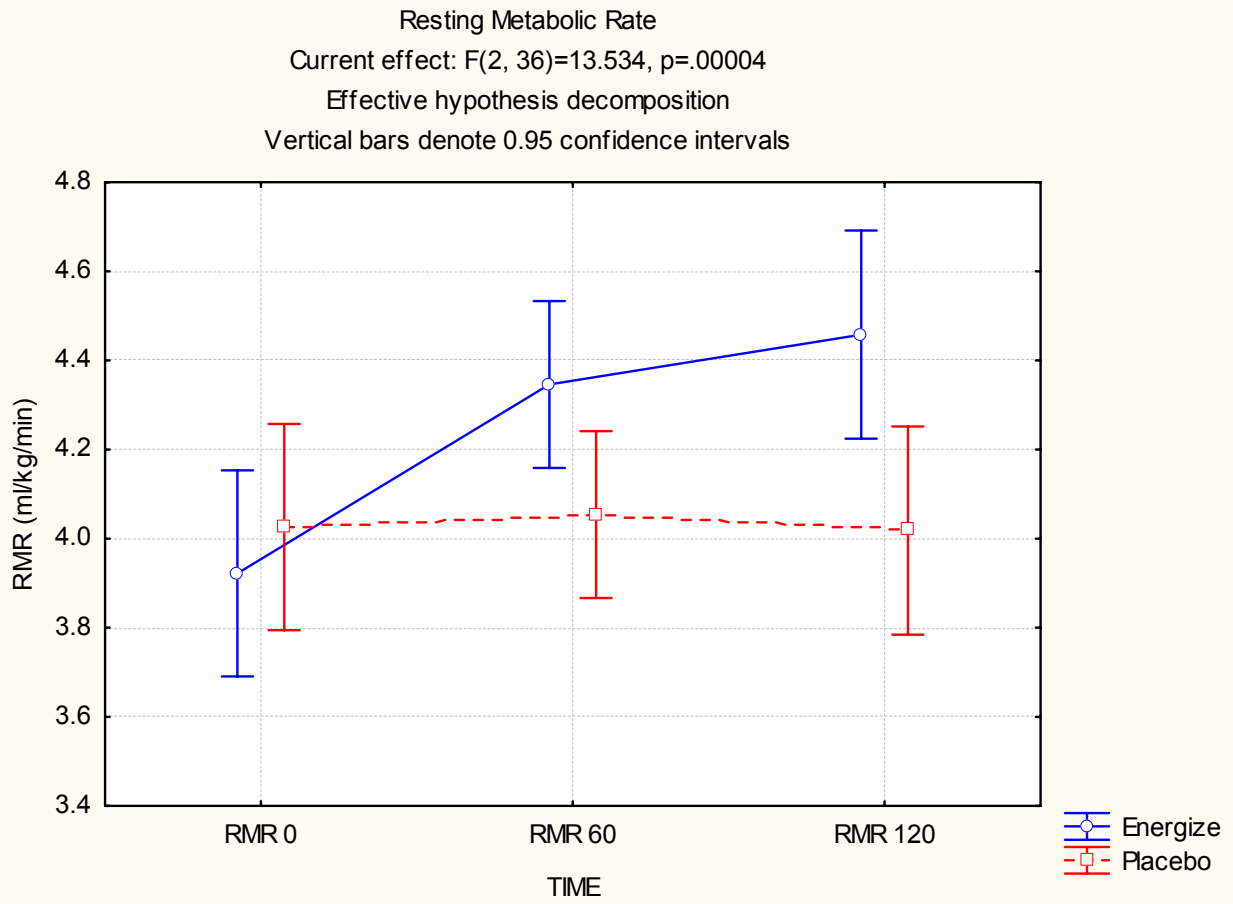
	Mean	Std.Dv.	N	Diff.	df	p
<b>RMR 0</b>	3.922000	0.318845				
<b>RMR 0</b>	3.922000	0.318845	10	0.000000	9	1.000000
<b>RMR 0</b>	3.922000	0.318845				
<b>RMR 60</b>	4.346000	0.216343	10	-0.424000	9	0.000741
<b>RMR 0</b>	3.922000	0.318845				
<b>RMR 120</b>	4.458000	0.331790	10	-0.536000	9	0.004718
<b>RMR 60</b>	4.346000	0.216343				
<b>RMR 0</b>	3.922000	0.318845	10	0.424000	9	0.000741
<b>RMR 60</b>	4.346000	0.216343				

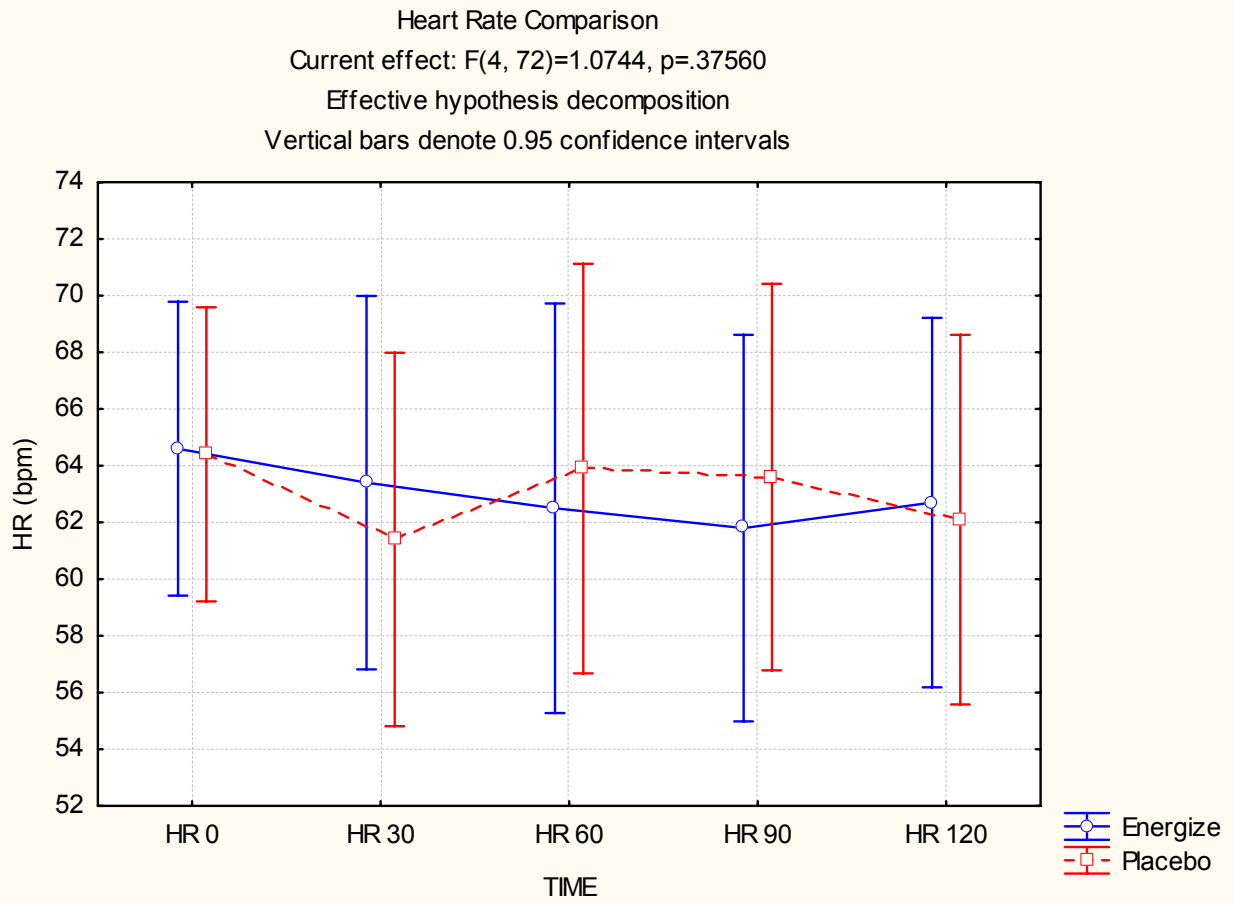
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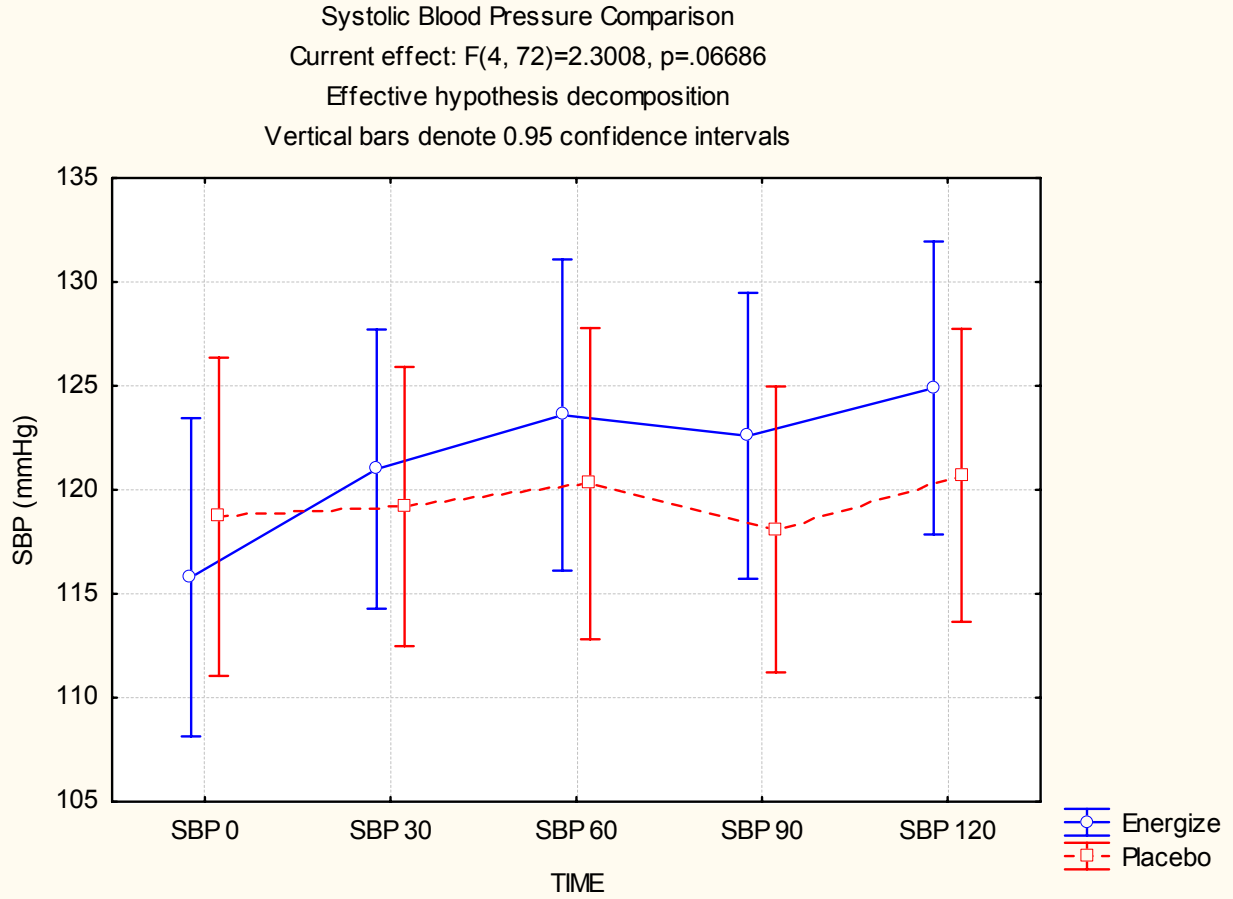
<b>RMR 60</b>	4.346000	0.216343	10	0.000000	9	1.000000
<b>RMR 60</b>	4.346000	0.216343				
<b>RMR 120</b>	4.458000	0.331790	10	-0.112000	9	0.173585
<b>RMR 120</b>	4.458000	0.331790				
<b>RMR 0</b>	3.922000	0.318845	10	0.536000	9	0.004718
<b>RMR 120</b>	4.458000	0.331790				
<b>RMR 60</b>	4.346000	0.216343	10	0.112000	9	0.173585
<b>RMR 120</b>	4.458000	0.331790				
<b>RMR 120</b>	4.458000	0.331790	10	0.000000	9	1.000000

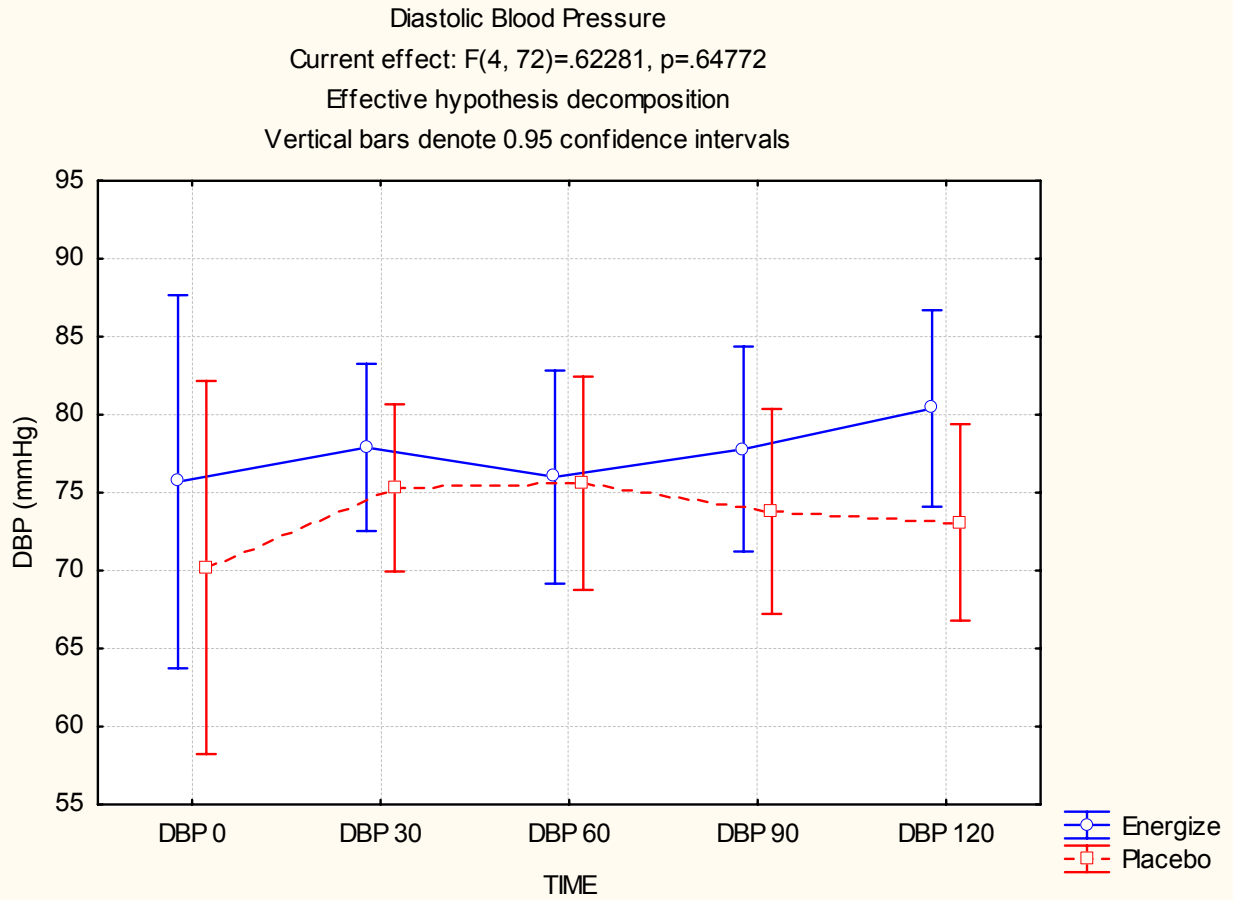
Dependent t-test for Placebo Group

	<b>Mean</b>	<b>Std.Dv.</b>	<b>N</b>	<b>Std.Dv.</b>	<b>df</b>	<b>p</b>
<b>RMR 0</b>	4.026000	0.375772				
<b>RMR 0</b>	4.026000	0.375772	10	0.000000	9	1.000000
<b>RMR 0</b>	4.026000	0.375772				
<b>RMR 60</b>	4.054000	0.335036	10	0.061427	9	0.183336
<b>RMR 0</b>	4.026000	0.375772				
<b>RMR 120</b>	4.018000	0.370339	10	0.072541	9	0.735302
<b>RMR 60</b>	4.054000	0.335036				
<b>RMR 0</b>	4.026000	0.375772	10	0.061427	9	0.183336
<b>RMR 60</b>	4.054000	0.335036				
<b>RMR 60</b>	4.054000	0.335036	10	0.000000	9	1.000000
<b>RMR 60</b>	4.054000	0.335036				
<b>RMR 120</b>	4.018000	0.370339	10	0.073967	9	0.158165
<b>RMR 120</b>	4.018000	0.370339				
<b>RMR 0</b>	4.026000	0.375772	10	0.072541	9	0.735302
<b>RMR 120</b>	4.018000	0.370339				
<b>RMR 60</b>	4.054000	0.335036	10	0.073967	9	0.158165
<b>RMR 120</b>	4.018000	0.370339				
<b>RMR 120</b>	4.018000	0.370339	10	0.000000	9	1.000000

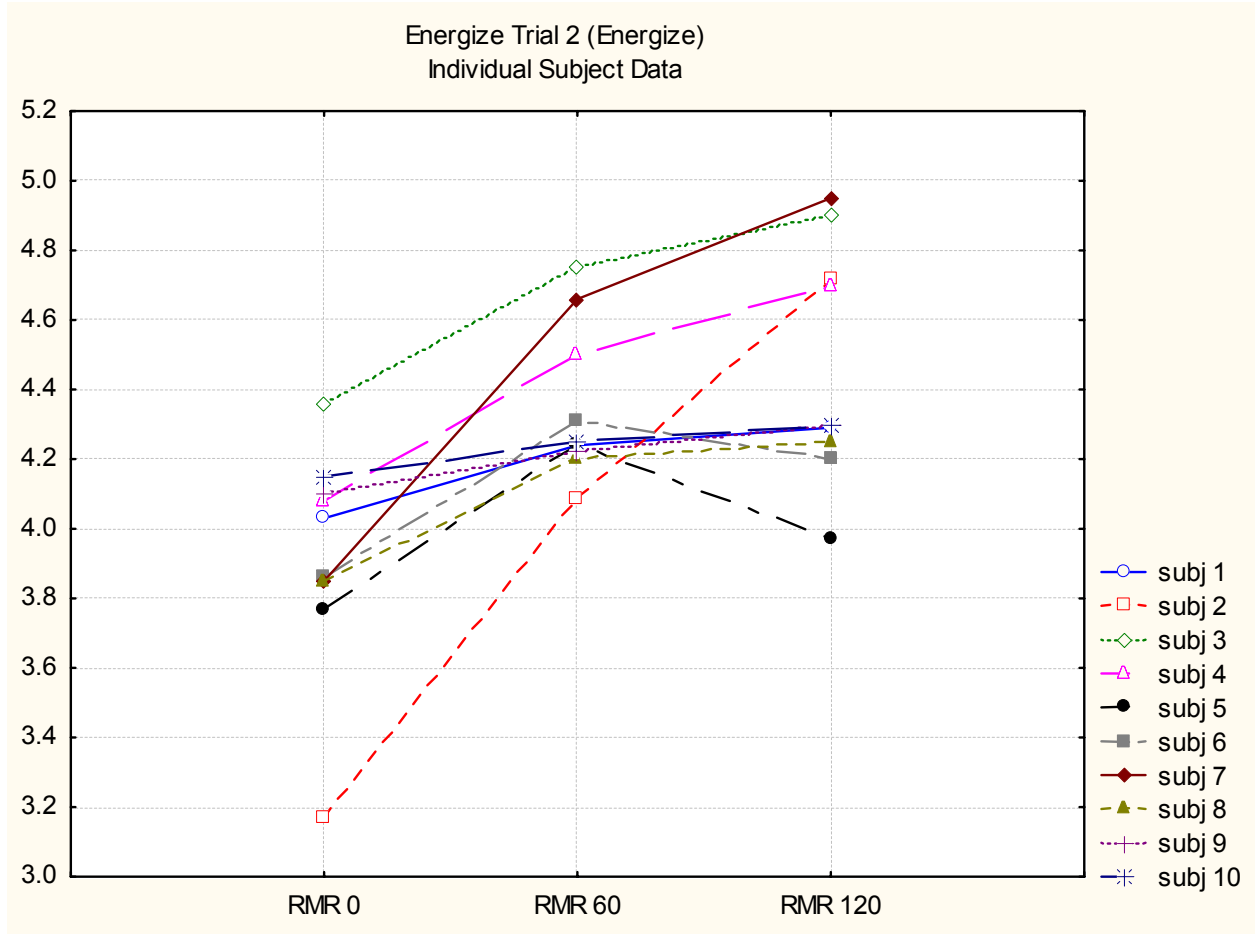




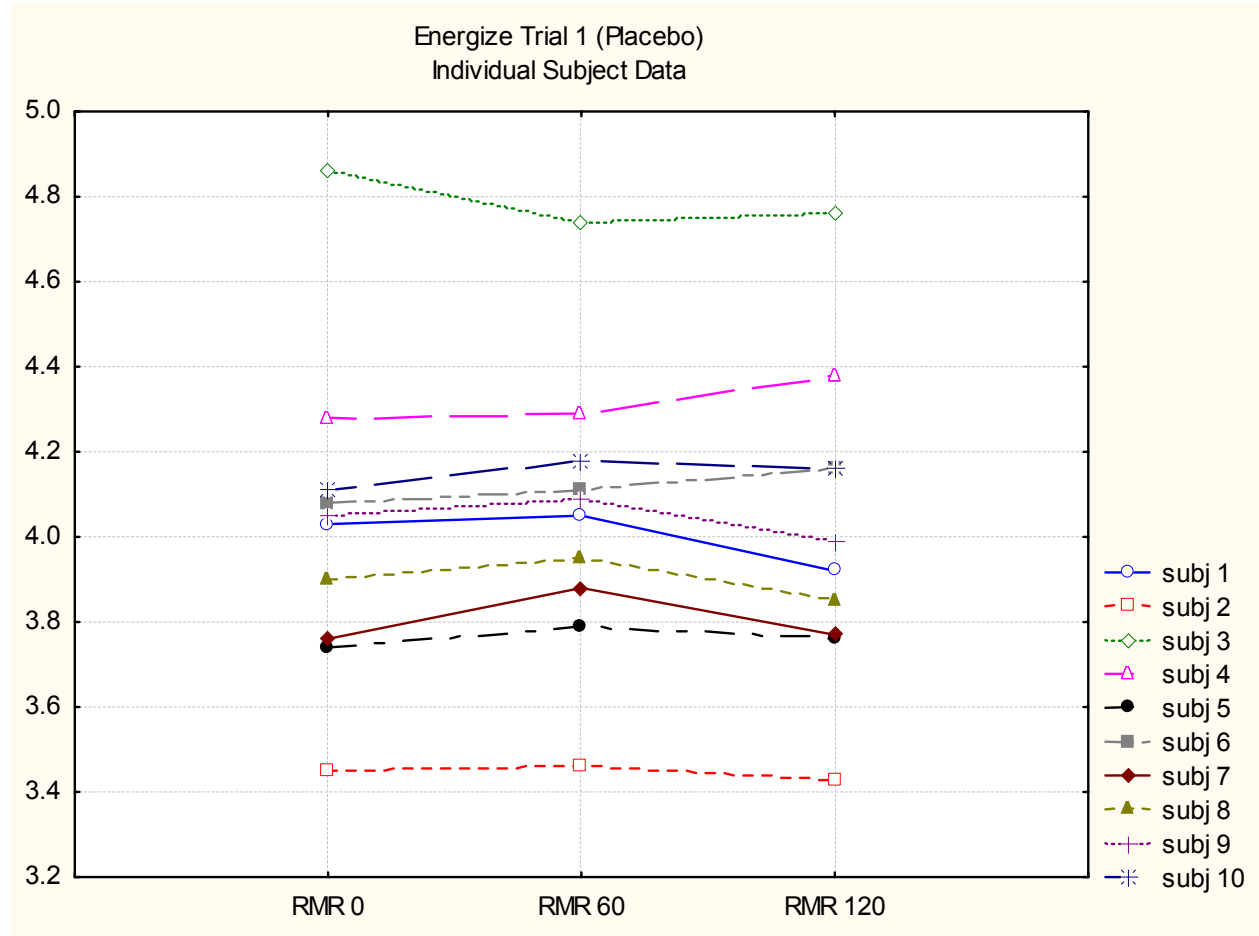








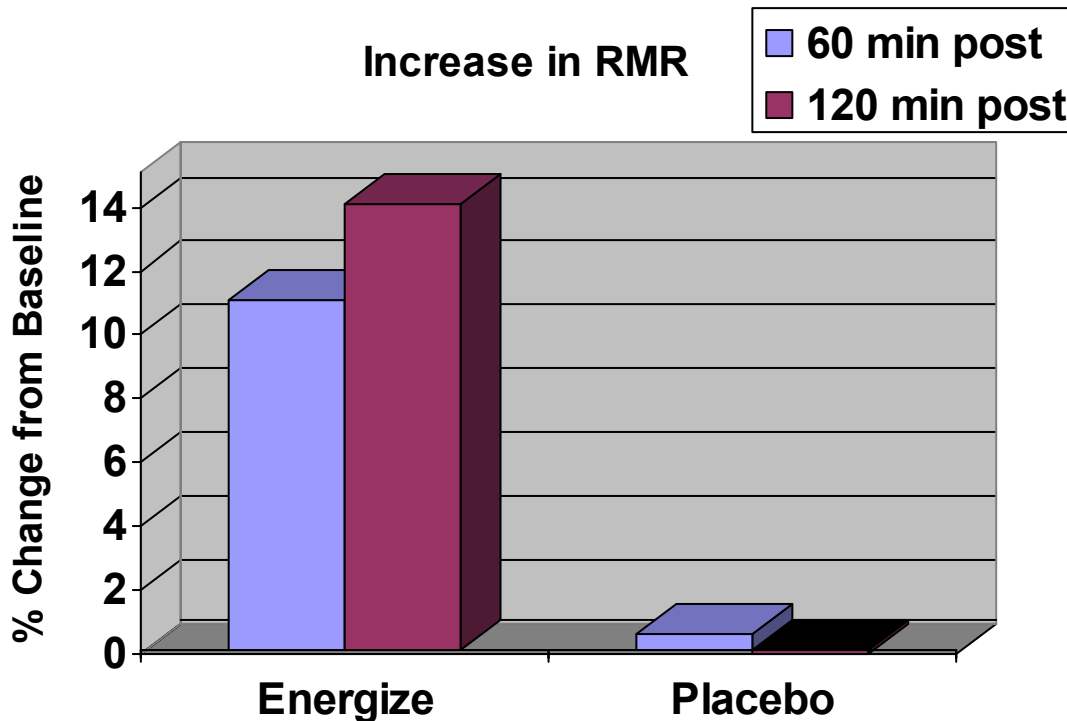
This graph represents individual subject data for resting metabolic rate under the energize condition. It can be compared to the following graph which represents the resting metabolic rate data under the placebo condition for the same individual subjects.



This graph represents individual subject data for resting metabolic rate under the placebo condition. It can be compared to the previous graph which represents the resting metabolic rate data under the energize condition for the same individual subjects.

## SUMMARY

A fundamental concept behind weight loss is that calories expended must be greater than calories consumed. Total daily energy expenditure is the sum of three basic parts: resting metabolic rate (RMR), the thermic effect of food (TEF), and the thermic effect of activity (TEA). For most of us, the rate at which we burn calories at rest (RMR) comprises 60-70% of our total daily caloric expenditure. Thus, any factor that increases RMR (even to a small extent) gives us more “energy”, and can play a major role in weight loss. Recently, researchers from the Ohio Research Group of Exercise Science and Sports Nutrition performed a study to examine the effects of a single dose (two tablets) of Energize™ on RMR. Using a placebo-controlled, double-blind, cross-over design, five men and five women had their RMR measured by indirect calorimetry (where the oxygen and carbon dioxide content of expired air is quantified) prior to supplementation and again during the last ten minutes of each hour for two hours post-ingestion. Results indicated that a single dose (two tablets) of Energize™ increased RMR by 11-15% above baseline, and that the effects on metabolism lasted for at least two hours. For two subjects, the increase was greater than 25% during the Energize™ trial. Heart rate and blood pressure were no different between trials. Given these impressive results from acute supplementation, researchers are eager to study the effects of chronic Energize™ supplementation on weight loss and changes in body composition.



### Acknowledgements

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