

**THE ACUTE METABOLIC, HEMODYNAMIC, AND  
PSYCHOLOGICAL EFFECTS OF FASTIN<sup>R</sup>-XR,  
A COMMERCIAL WEIGHT LOSS PRODUCT**

## GENERAL INFORMATION

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## Table of Contents

<b>Background</b> .....	<b>Page 5</b>
Investigational Agent	
Dose Rationale	
Trial Conduct	
Population	
<b>Trial Objectives</b> .....	<b>Page 5</b>
<b>Trial Design</b> .....	<b>Page 6</b>
Study Design/Type	
Randomization	
Trial Treatment	
Duration	
<b>Selection of Subjects</b> .....	<b>Page 6</b>
Inclusion Criteria	
Exclusion Criteria	
<b>Treatment of Subjects</b> .....	<b>Page 7</b>
Treatment Conditions	
Study Design	
Test Session Protocol	
<b>Statistical Plan</b> .....	<b>Page 9</b>
Statistical Methods	
Subject Population(s) for Analysis	
Significance	

## PRELIMINARY RESULTS

**Research Participants** ..... **Page 10**

**Physiological Outcomes** ..... **Page 11**

Oxygen Consumption

Minute Ventilation

Oxygen Extraction

Heart Rate

Oxygen Pulse

Systolic Blood Pressure

Diastolic Blood Pressure

**Profile of Mood States Inventory** ..... **Page 18**

Total Mood Disorder (TMD)

Vigor-Activity

Tension-Anxiety

Depression-Dejection

Anger-Hostility

Fatigue-Inertia

Confusion-Bewilderment

# **1 Background**

## **1.1 Investigational Agent**

This study investigated the acute physiological and psychological effects of Fastin<sup>R</sup>-XR, a commercial weight control product.

## **1.2 Dose Rationale**

This study examined the effects of one dose of the commercial product Fastin<sup>R</sup>-XR in comparison with three other study conditions including 1) 300 mg caffeine anhydrous 2) 250 mg acacia rigidula extract and 3) a placebo condition (cellulose). Thus, the study dosages represented treatments that are commonly self-administered from over the counter sources.

## **1.3 Trial Conduct**

This study was conducted in compliance with the protocol approved by the Institutional Review Board, and according to Good Clinical Practice standards.

## **1.4 Population**

This study included males 18 to 45 years of age. Study participants needed to report themselves as 'recreationally active', which was operationally defined as participating in at least two exercise sessions per week during the previous six month period. Inclusion criteria also included regular ingestion of caffeine as indicated by self-report of daily intake, on most days, of more than one caffeine containing beverage (coffee, cola, energy drink, etc). Known metabolic or cardiovascular disease, or psychiatric disorders excluded participation in this study.

# **2 Trial Objectives**

The primary objective of this study was to determine the effects of a single dose of the commercial product Fastin<sup>R</sup>-XR on resting energy expenditure, heart rate and blood pressures, and measures of psychological mood. Secondary objectives included examination of those same outcomes measures in acute response to a single 300 mg dose of caffeine anhydrous and in response to 250 mg of acacia rigidula extract.

### **3 Trial Design**

#### **3.1 Study Design/Type**

This study utilized a randomized, double blinded, crossover, placebo controlled research design.

#### **3.2 Randomization**

All research subjects were asked to participate in four study conditions, one condition per testing session. The order of treatments was randomized among participants in a double blind fashion.

#### **3.3 Trial Treatment**

This study examined the acute effects of four different treatments. These treatments are classified as dietary supplements by the Dietary Supplement Health and Education Act of 1994. These four treatments included:

- 1) One dose of the commercial product, Fastin<sup>R</sup>-RX
- 2) 300 mg caffeine anhydrous
- 3) 250 mg acacia rigidula extract and
- 4) Placebo condition (cellulose).

The doses of the four treatments were similar in a look-a-like fashion with two capsules of the same size and color per dose.

#### **3.4 Duration**

This study involved four testing sessions that were performed on four separate days with 2 – 7 days between. Thus, it was expected that each study participant would complete the study in two to four weeks.

### **4 Selection of Subjects**

#### **4.1 Inclusion Criteria**

This study included ten males between 18 and 45 years of age. Study participants reported themselves as ‘recreationally active’, which was operationally defined as participating in at least two exercise sessions per week during the previous six month period. Inclusion criteria also included regular ingestion of caffeine as indicated by self-report of daily intake, on most days, of more than one caffeine containing beverage (coffee, cola, energy drink, etc)

#### **4.2 Exclusion Criteria**

This study excluded persons that reported a history of metabolic or cardiovascular disease or psychiatric disorders.

## **5 Treatment of Subjects**

### **5.1 TREATMENT CONDITIONS**

This study involved four different treatment condition that were each administered in oral format during separate test sessions. The four dietary supplement treatments included:

- 1) One dose of the commercial product, Fastin<sup>R</sup>-RX
- 2) 300 mg caffeine anhydrous
- 3) 250 mg acacia rigidula extract and
- 4) Placebo condition (cellulose).

The four conditions were presented in a look-alike fashion (one dose was two capsules of the same size and color).

### **5.2 STUDY DESIGN**

This study utilized a prospective, randomized, double-blind, placebo-controlled research design. Each research participant completed five study sessions including one orientation/intake session followed by four treatments sessions. Each treatment session examined the acute metabolic responses of one of four different treatments: Fastin<sup>R</sup>-XR, acacia rigidula extract, caffeine, and placebo (cellulose). The four treatments were randomized in order with at least 48 hours between test sessions.

### **5.3 TEST SESSION PROTOCOL**

During each of four testing sessions, the research subjects completed a three hour resting metabolic study. The testing protocol was consistent between sessions with each session examining the acute effects of one of four different test conditions. The four conditions included Fastin<sup>R</sup>-XR, acacia rigidula extract, caffeine, and placebo (cellulose). Treatment conditions were performed in randomized order with at least 48 hours between each session. The test sessions lasted approximately four hours.

All test procedures were non-invasive (collection of expired air, measurement of HR and BP, written responses) and presented minimal risks to the study participants.

Study participants were asked to report to the testing center at 7:00AM after a 12 hour fast. They were directed to refrain from caffeine or nicotine on the day of testing and to avoid extremely vigorous exercise the day prior.

### **Physiological Assessment**

Subjects were positioned in a semi-recumbent position in a semi-darkened room and fitted with a neoprene mask containing a Medgraphics preVent™ pneumotach. This open flow spirometry metabolic analysis system measured expired gases via indirect calorimetry and determine values of oxygen consumption ( $\text{VO}_2$ ) as an indication of Resting Energy Expenditure (REE). Values of  $\text{VO}_2$  were determined for 15 minute intervals at baseline as well as at 1hr, 2hrs, and 3 hrs following ingestion of the respective treatment for that session.

Hemodynamic activity was also examined at those same time points (baseline, 1hr, 2hr, 3hr) by measurement of heart rate and blood pressure. Heart rate will be determined using a wireless monitor and blood pressures was determined by an automated  
Following collection of fifteen minutes of baseline data, subjects completed the psychological test (POMS) for the baseline rest period. The metabolic masks were then removed in order to ingest the respective treatment for that test session (Fastin, acacia rigidula, caffeine, placebo). At 1hr, 2hrs, and 3hrs after supplement ingestion, the mask was replaced for 15 minutes of metabolic data collection.

### **Psychological Mood Assessment**

The profile of mood states (POMS-SF) was used to determine psychological measures at baseline, 1hr post, 2 hrs post, and 3 hrs post ingestion. The POMS-SF consists of 39 words or phrases in a Likert format questionnaire which provides measures of specific mood states. It provides measures of tension, depression, anger, vigor, fatigue and confusion. The survey consists of asking each subject to describe their feelings of energy, fatigue, alertness and focus at that moment.



## **6 Statistical Plan**

### **6.1 Statistical Methods**

The data derived from this study will be analyzed using two-way Analysis of Variance (ANOVA) with four levels of time (baseline, 1hr, 2hr, 3hr) and four levels of condition (Fastin<sup>R</sup>-XR, caffeine anhydrous, acacia rigidula extract, placebo). Post-hoc paired T-tests tests will be used to examine for statistically significant differences between conditions at matched time points.. Statistical significance will be accepted with a p value  $\leq 0.05$ .

### **6.2 Subject Population for Analysis**

A power analysis, based on the assumption of a very strong effect size (0.9) with moderate power level (0.7), suggested 10 subjects were needed for this study. With a total of five study encounters with up to four hours per session, it was reasonable to expect a considerable attrition rate. Only subjects that complete all five study sessions were included in the statistical analysis.

### **6.3 Significance**

The level of statistical significance accepted in this trial was  $p \leq 0.05$ .

## Research Participants

Ten men with a mean age of 28.5 years voluntarily participated in this investigation and completed all testing sessions. The demographic information for the study subjects is provided in Table 1. Body mass ranged from 70.3 kg (155 lbs) to 117.0 kg (258.5 lbs) with a mean value of 88.3 kg (194.6). Mean height was 178.4 cm (70.2 inches).

There were no adverse events noted in any of the subject testing sessions.

**Table 1: Participant Demographics**

	<u>Mean ± SD</u>	<u>Range</u>
N	10	
Gender	Male	
Age (years)	28.5 ± 5.8	20.9 – 39.3
Bodymass (lbs)	194.6 ± 36.0	155.0 – 258.5
Bodymass (kg)	88.3 ± 16.3	70.3 – 117.0
Height (inches)	70.2 ± 2.9	65.5 – 74.0
Height (cm)	178.4 ± 7.3	166.4 - 188.0

## Oxygen Consumption

The mean values of oxygen consumption for the four study groups across the four time points are provided in Table 2A. Preliminary analysis (paired T-tests) indicated that there were no significant differences between groups in values of  $VO_2$  at baseline. However, Fastin<sup>R</sup>-XR produced significantly greater ( $p < 0.05$ ) values of  $VO_2$  than the other three conditions (Placebo, Caffeine, and Acacia) at 1hr, at 2hrs, and at 3hrs post ingestion of the study supplements. Caffeine produced significantly greater values of oxygen consumption than placebo at 1hr and 2hrs post ingestion. Table 2B displays the mean changes in  $VO_2$  from baseline with each of the four study conditions. Figure 2 graphically shows the relative changes (% differences) from baseline.

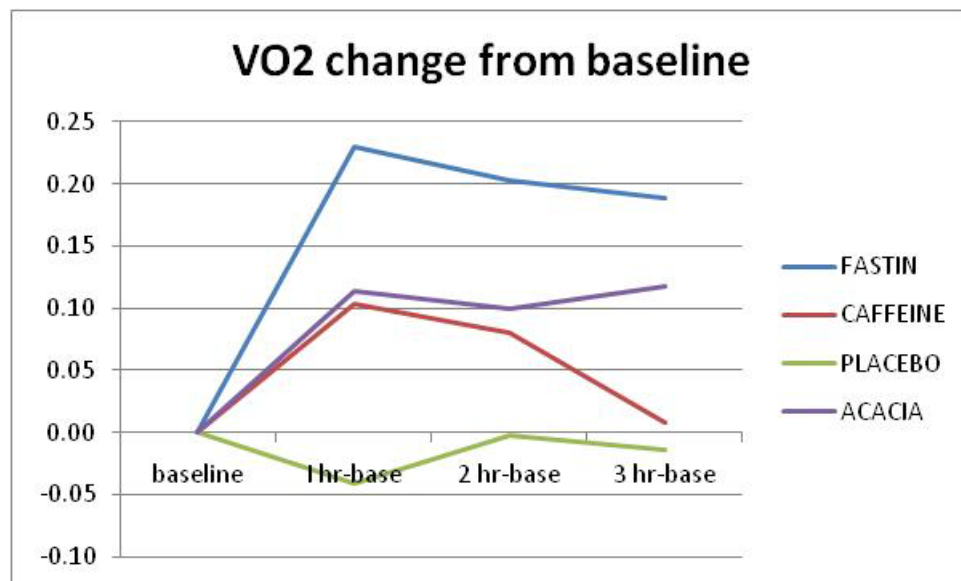
**Table 2A: Mean values of Oxygen Consumption (ml/min)**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	242.4	235.6	237.5	236.7
CAFFEINE	238.2	260.4	259.0	245.6
ACACIA	227.4	255.2	248.8	256.6
FASTIN	234.4	283.5	278.8	271.6

**Table 2B: Mean changes in Oxygen Consumption from baseline (ml/min)**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	-6.72	-4.81	-5.70
CAFFEINE	+22.1	+20.75	+7.36
ACACIA	+27.87	+21.46	+29.27
FASTIN	+49.11	+44.46	+37.24

**Figure 2: Relative changes in  $VO_2$  from baseline**



## Minute Ventilation

Table 3A presents the mean values of minute ventilation for the four study groups across the four time points. Analysis indicated that there were no significant differences between groups at baseline. However, analysis showed that Fastin<sup>R</sup>-XR produced significantly greater ( $p < 0.05$ ) values of VE than the other three conditions (Placebo, Caffeine, and Acacia) at 1hr, at 2hrs, and at 3hrs post ingestion of the study supplements. Fastin<sup>R</sup>-XR also produced greater values of VE than Acacia and Caffeine at 1hr and 2hrs post-ingestion. The only other significant difference detected between groups was greater VE with caffeine at 1hr post compared with placebo. Table 3B displays the mean changes in VE from baseline with each of the four study conditions. Figure 3 graphically shows the relative changes (% differences) from baseline.

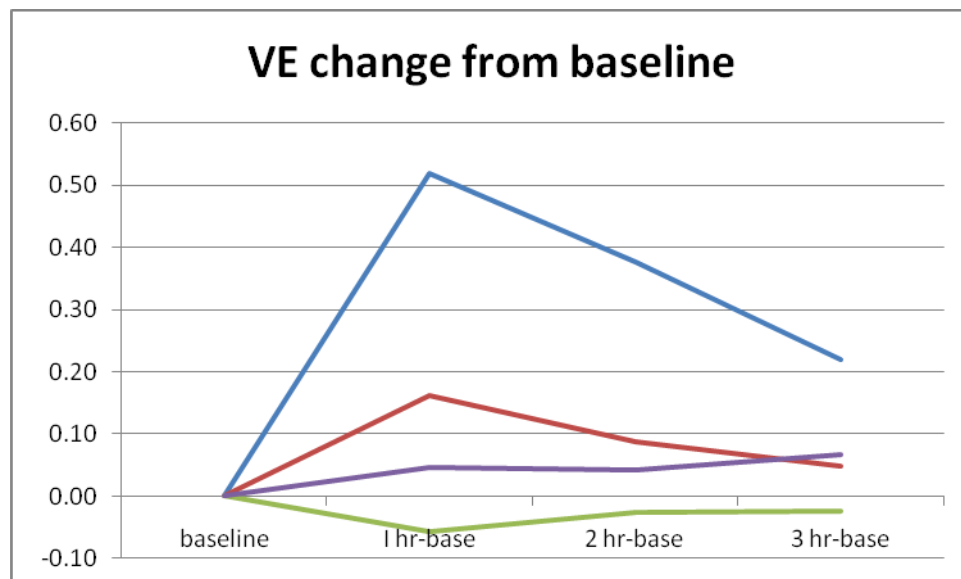
**Table 3A: Mean values of Minute Ventilation (l/min)**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	6.33	5.98	6.18	6.18
CAFFEINE	6.31	7.25	6.88	6.62
ACACIA	6.33	6.62	6.57	6.76
FASTIN	6.30	9.34	8.50	7.60

**Table 3B: Mean changes in Minute Ventilation from baseline (l/min)**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	-0.34	-0.14	-0.14
CAFFEINE	+0.94	+0.57	+0.31
ACACIA	+0.29	+0.24	+0.43
FASTIN	+3.05	-2.20	+1.30

**Figure 3: Relative changes in VE from baseline**



## Oxygen Extraction

The values of oxygen extraction were calculated as oxygen consumption divided by minute ventilation ( $VO_2/VE$ ). Mean values of oxygen extractions for the four study groups across the four time points are provided in Table 4A. Analysis indicated that there were no significant differences between groups in values of  $O_2$  extraction at baseline. However, Fastin<sup>R</sup>-XR produced significantly lower values of oxygen extraction ( $p < 0.05$ ) than Acacia at 1hr, at 2hrs, and at 3hrs post ingestion and significantly lower than Caffeine and Placebo at 1 hr post. Table 4B displays the mean changes in oxygen extraction from baseline with each of the four study conditions. Figure 4 graphically shows the relative changes (% differences) from baseline.

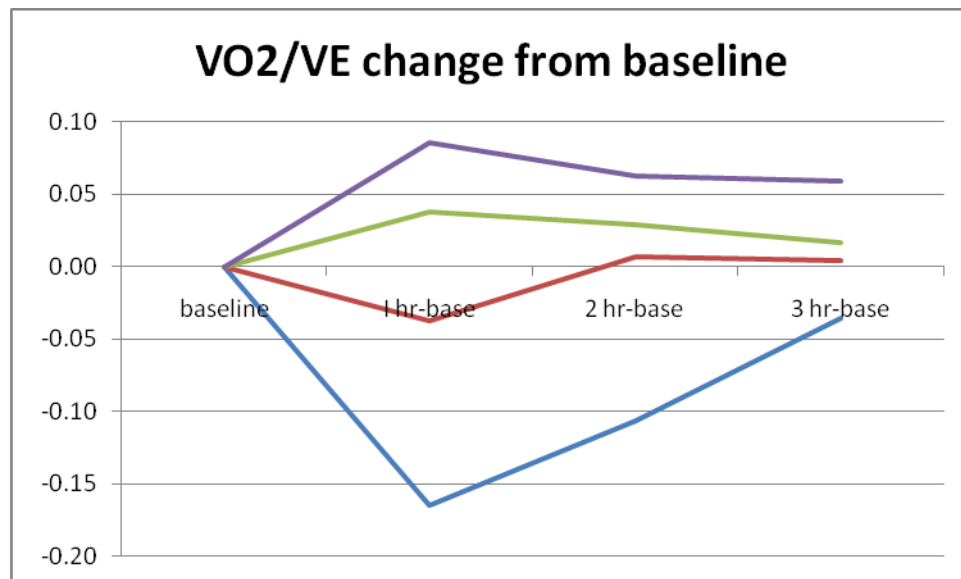
**Table 4A: Mean values of Oxygen Extraction ( $VO_2/VE$ )**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	0.0383	0.0395	0.0389	0.0385
CAFFEINE	0.0380	0.0362	0.0380	0.0380
ACACIA	0.0363	0.0392	0.0384	0.0384
FASTIN	0.0376	0.0313	0.0336	0.0362

**Table 4B: Mean changes in Oxygen Extraction from baseline**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	+0.00119	+0.00061	-0.00019
CAFFEINE	-0.00181	-0.00004	-0.00002
ACACIA	+0.00290	+0.00204	+0.00204
FASTIN	-0.00631	-0.00398	-0.00144

**Figure 4: Relative changes in Oxygen Extraction from baseline**



## Heart Rate

Table 5A shows the mean values of heart rate across the four time points are provided in Table 2A. Preliminary analysis (paired T-tests) indicated that there were no significant differences between groups in values of HR at baseline or at 1hr post ingestion. However, Fastin<sup>R</sup>-XR produced significantly greater ( $p < 0.05$ ) values of HR than Placebo or Caffeine at 2hrs and 3hrs post and FastinR-XR produced significantly greater values of HR compared with Acacia at 3hrs post ingestion only. Table 5B displays the mean changes in HR from baseline with each of the four study conditions. Figure 5 graphically shows the relative changes (% differences) from baseline.

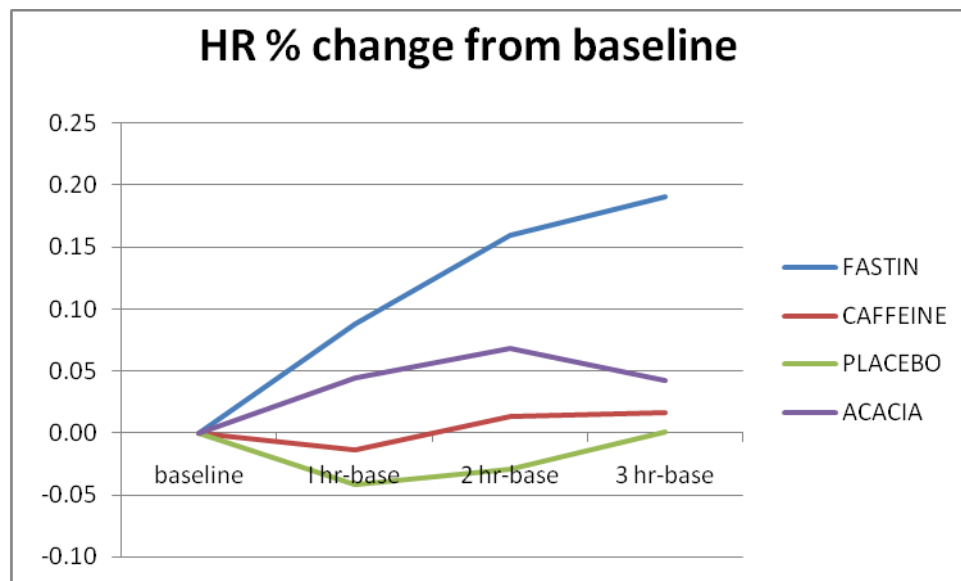
**Table 5A: Mean values of Heart Rate (beats/min)**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	64.2	61.4	62.2	64.2
CAFFEINE	61.6	60.7	62.0	62.3
ACACIA	59.4	61.9	63.5	61.9
FASTIN	60.8	65.6	70.2	71.9

**Table 5B: Mean changes in Heart Rate from baseline (beats/min)**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	-2.80	-2.00	0.00
CAFFEINE	-0.90	+0.40	+0.70
ACACIA	+2.50	+4.10	+2.50
FASTIN	+4.80	+9.40	+11.10

**Figure 5: Relative changes (%) in HR from baseline**



## Oxygen Pulse

Oxygen Pulse was calculated as the ratio of  $VO_2$  / HR and is useful as an indicator of stroke volume. Table 6A shows the mean values of oxygen pulse across the four time points. Analysis indicated that there were no significant differences between groups in values of O<sub>2</sub> pulse at baseline or at any point post ingestion. Neither was there a time effect within groups. Table 6B displays the mean changes in O<sub>2</sub> pulse from baseline with each of the four study conditions. Figure 6 graphically shows the relative changes (% differences) from baseline.

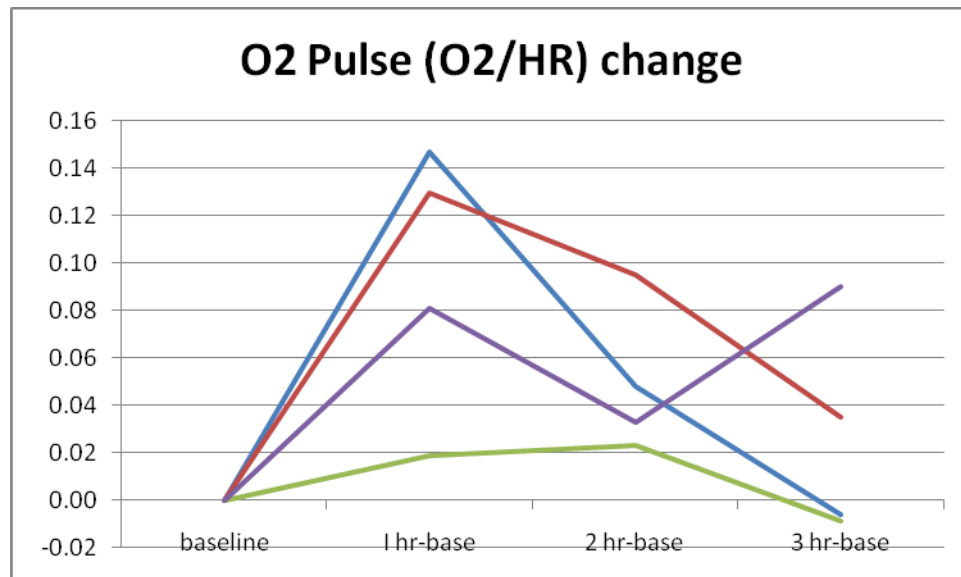
**Table 6A: Mean values of Oxygen Pulse (ml/beat)**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	3.85	3.90	3.87	3.78
CAFFEINE	4.00	4.49	4.33	4.03
ACACIA	3.88	4.18	4.01	4.22
FASTIN	3.92	4.50	4.10	3.92

**Table 6B: Mean changes in Oxygen Pulse from baseline (ml/beat)**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	+0.050	+0.184	-0.066
CAFFEINE	+0.454	+0.324	+0.029
ACACIA	+0.297	+0.126	+0.337
FASTIN	+0.577	+0.180	+0.002

**Figure 6: Relative changes (%) in O<sub>2</sub> Pulse from baseline**



## Systolic Blood Pressure

Mean values of systolic blood pressure are provided in Table 7A. Preliminary analysis (paired T-tests) indicated that there were no significant differences between groups in values of SBP at baseline. However, Fastin<sup>R</sup>-XR produced significantly greater ( $p < 0.05$ ) values of SBP than each of the other three study conditions (Placebo, Caffeine, Acacia) at 1hr, 2hrs and 3hrs post ingestion. Table 7B displays the mean changes in SBP from baseline with each of the four study conditions. Figure 7 graphically shows the relative changes (% differences) from baseline.

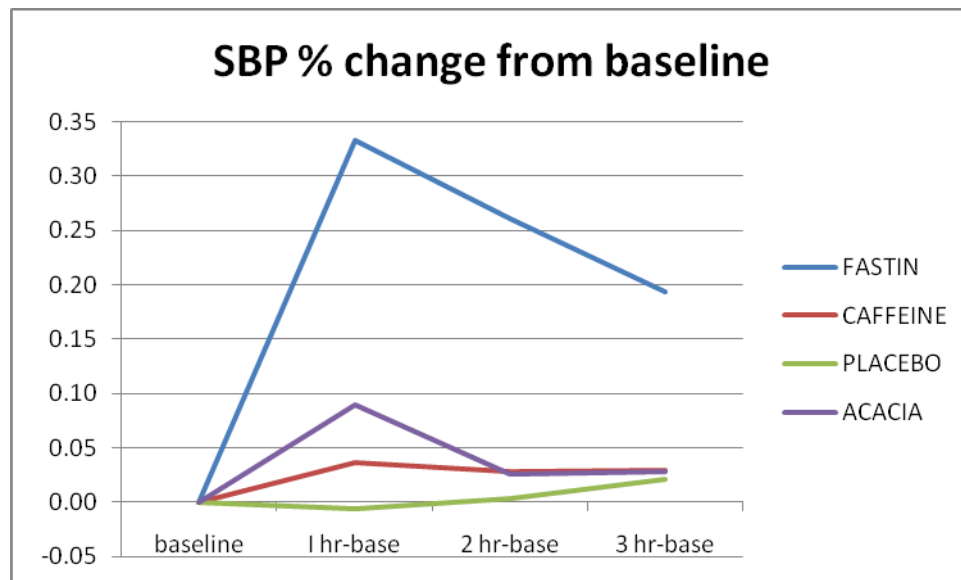
**Table 7A: Mean values of Systolic Blood Pressure (mmHg)**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	122.1	120.8	121.7	124.1
CAFFEINE	123.8	127.9	127.1	127.1
ACACIA	119.4	130.4	122.8	123.1
FASTIN	117.9	155.7	147.5	139.9

**Table 7B: Mean changes in Systolic Blood Pressure from baseline (mmHg)**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	-1.3	-0.4	+2.0
CAFFEINE	+4.1	+3.3	+3.3
ACACIA	+10.7	+3.10	+3.40
FASTIN	+37.8	+29.6	+22.0

**Figure 7: Relative changes (%) in SBP from baseline**





## Diastolic Blood Pressure

Preliminary analyses (paired T-tests) indicated that there were no significant differences at baseline between study groups in mean values of DBP. FastinR-XR produced significantly greater ( $p < 0.05$ ) mean values of DBP than Placebo and Acacia at 1 hr post and at 2 hrs post and significantly greater values compared with Caffeine at 1 hr post ingestion. There were no significant differences detected between groups in DBP at 3hrs post. Table 8A provides the mean values of DBP for the four study groups across the four time points and Table 8B provides the mean changes in DBP from baseline. Figure 8 displays the relative changes (%) in DBP from baseline for each of the study groups.

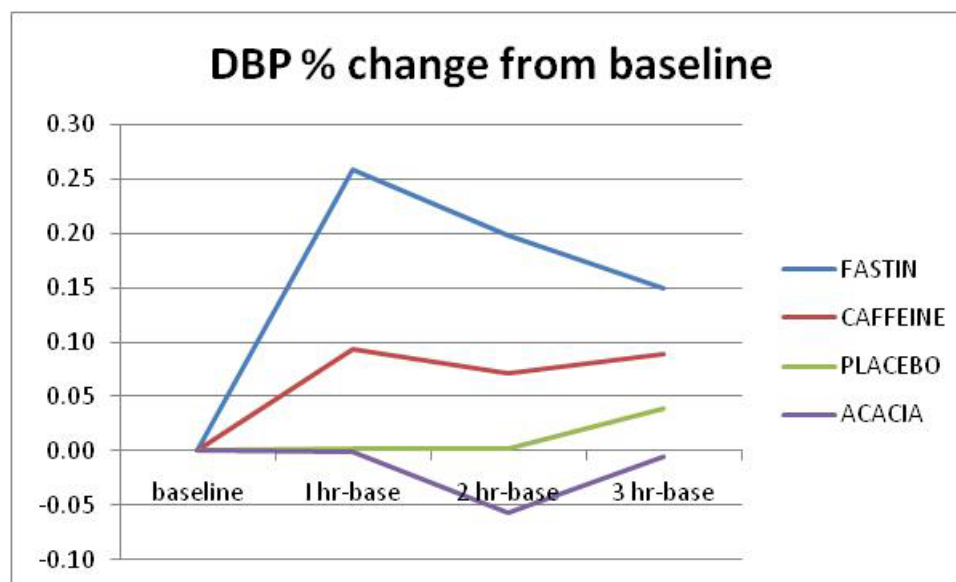
**Table 8A: Mean values of Diastolic Blood Pressure (mmHg)**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	62.3	62.4	62.5	64.7
CAFFEINE	62.0	67.8	66.3	67.5
ACACIA	64.4	63.9	60.7	63.8
FASTIN	62.8	77.9	74.0	71.3

**Table 8B: Mean changes in Diastolic Blood Pressure from baseline (mmHg)**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	+0.1	+0.2	+2.4
CAFFEINE	+5.8	+4.3	+5.5
ACACIA	-0.5	-3.7	-0.6
FASTIN	+15.1	+11.2	+8.5

**Figure 8: Relative changes in DBP (%) from baseline**



## **Profile of Mood States**

The Profile of Mood States (POMS) is a factor derived inventory that assesses six identifiable mood states. The POMS assessment is a self-report measure in which the individual rates how they relate to particular affective/mood conditions.

The six mood states assessed with the POMS include tension-anxiety; depression-dejection; anger-hostility; fatigue-inertia; confusion-bewilderment; and vigor-activity

## **Total Mood Disorder**

The Total Mood Disorder (TMD) score is an overall indication of mood in which the score is derived by summing the scores of five of the POMS factors generally considered as non-positive in nature (tension-anxiety; depression-dejection; anger-hostility; fatigue-inertia; confusion-bewilderment) and subtracting the scores of one positive factor (vigor-activity).

**Tension-Anxiety** is a factor that is used to describe states of heightened musculoskeletal tension

**Depression-Dejection** is a factor that indicates mood of depression and personal inadequacies.

**Anger-Hostility** is reported to indicate moods of anger and antipathy towards others.

**Vigor-Activity** is described as moods of vigorousness and high energy.

**Fatigue-Inertia** represents moods of weariness and low energy.

**Confusion-Bewilderment** is characterized by bewilderment and muddleheadedness.

**Total Mood Disorder** scores measured during the four study conditions and across the four time points are displayed in Table 9A. Preliminary analyses (paired T-tests) indicated no significant differences ( $p>0.05$ ) at baseline. Fastin<sup>R</sup>-XR produced significantly lower values of TMD than the Placebo and the Acacia conditions at 1hr and 3 hrs post ingestion. There were no significant differences between Fastin<sup>R</sup>-XR and Caffeine at any time point. Table 9B and Figure 9 display the mean changes in TMD in each of the four study groups.

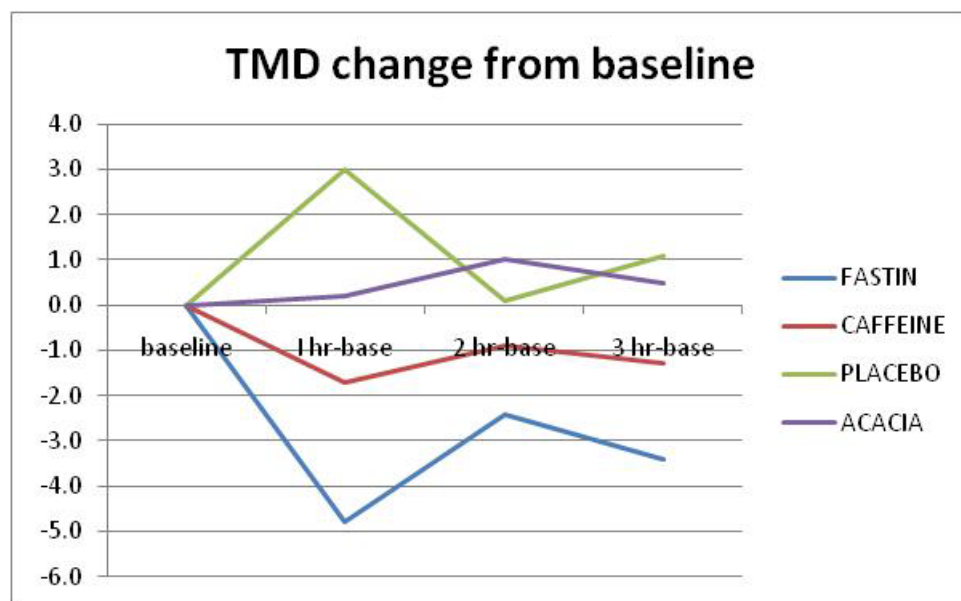
**Table 9A: Mean values of Total Mood Disorder (TMD)**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	-0.9	+2.1	-0.8	+0.2
CAFFEINE	+0.3	-1.4	-0.6	-1.0
ACACIA	-0.4	-0.2	+0.6	+0.1
FASTIN	+0.9	-3.9	-1.5	-2.5

**Table 9B: Mean changes in Total Mood Disorder from baseline**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	+3.0	+0.1	+1.1
CAFFEINE	-1.7	-0.9	-1.3
ACACIA	+0.2	+1.0	+0.5
FASTIN	-4.8	-2.4	-3.4

**Figure 9: Changes in TMD from baseline**



**VIGOR** scores for the four study conditions are provided in Table 10. Preliminary analyses indicates that there were no significant differences between groups at baseline, but the scores with the FastinR-XR condition were significantly greater ( $p>0.5$ ) than with Placebo or Caffeine or Acacia at 1hr, 2hrs and 3hrs post ingestion. Changes in Vigor from baseline values are displayed in Table 10B and Figure 10.

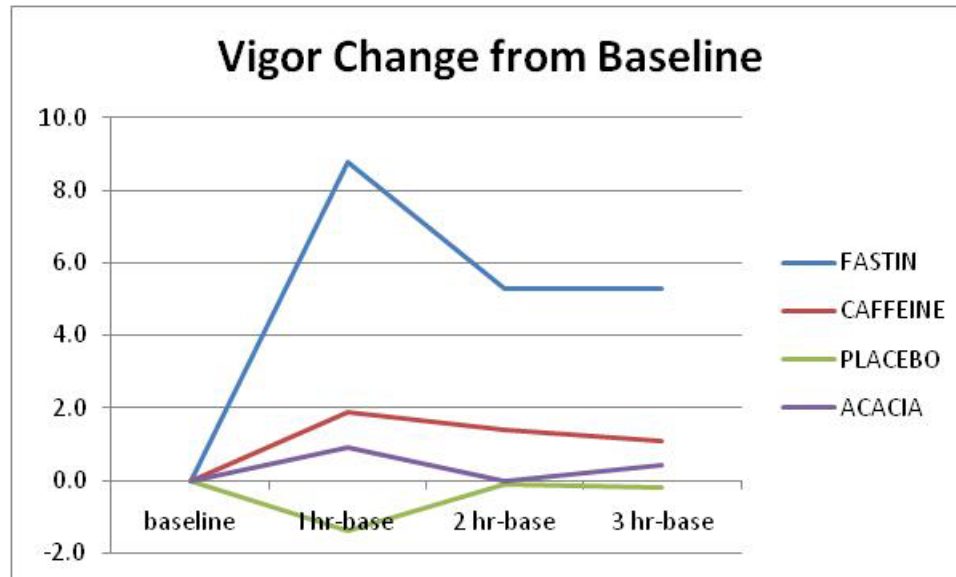
**Table 10A: Mean values of VIGOR**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	+3.0	+1.6	+2.9	+2.8
CAFFEINE	+1.6	+3.5	+3.0	+2.7
ACACIA	+1.4	+2.3	+1.4	+1.8
FASTIN	+1.3	+10.1	+6.6	+6.6

**Table 10B: Mean changes in VIGOR from baseline**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	-1.4	-0.1	-0.2
CAFFEINE	+1.9	+1.4	+1.1
ACACIA	+0.9	0.0	+0.4
FASTIN	+8.8	+5.3	+5.3

**Figure 10: Changes in Vigor from baseline**



**Tension** scores are presented in Table 11A. No statistically significant differences were detected between conditions at baseline. Analyses showed that Fastin<sup>R</sup>-XR Tension scores were significantly greater than Placebo and Acacia at 1hr, 2hrs and 3hrs post ingestion and that the Fastin<sup>R</sup>-XR scores were significantly greater ( $p < 0.05$ ) than caffeine at 2hrs and 3 hrs post.

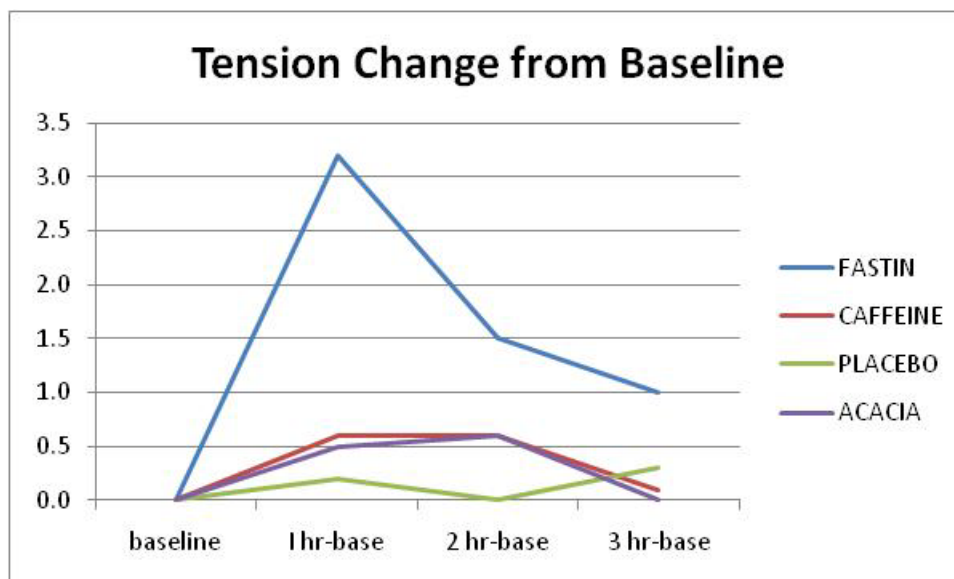
**Table 11A: Mean values of Tension**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	+0.3	+0.5	+0.3	+0.6
CAFFEINE	+0.2	+0.8	+0.8	+0.3
ACACIA	0.0	+0.5	+0.6	0.0
FASTIN	+0.6	+3.8	+2.1	+1.6

**Table 11B: Mean changes in Tension from baseline**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	+0.2	0.0	+0.3
CAFFEINE	+0.6	+0.6	+0.1
ACACIA	+0.5	+0.6	0.0
FASTIN	+3.2	+1.5	+1.0

**Figure 11: Changes in Tension from baseline**



**Depression** absolute scores are shown in Table 12A and the change in Depression scores from baseline are provided in Table 12B and Figure 12. There were no significant differences detected between FastinR-XR and any of the other three study conditions at any of the three time points examined.

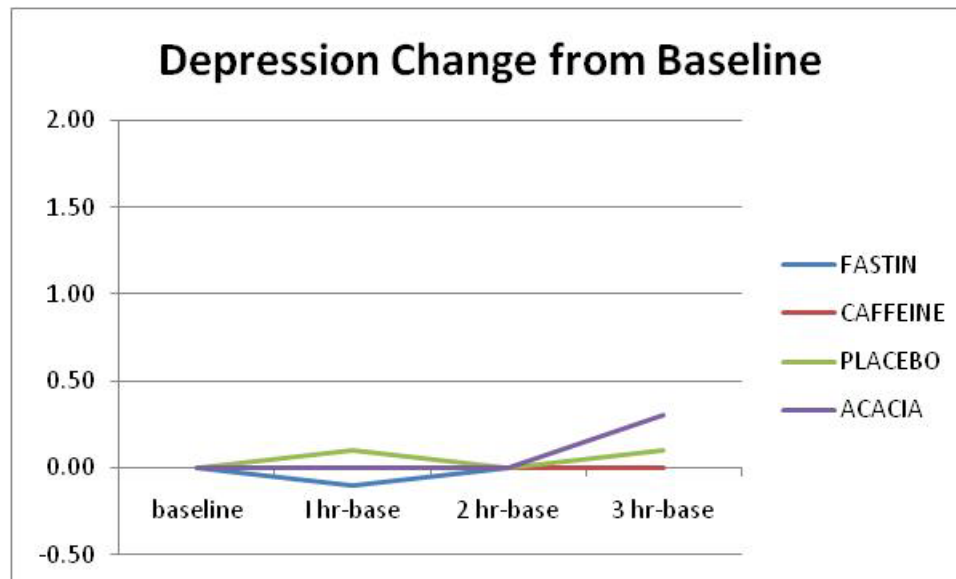
**Table 12A: Mean values of Depression**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	0.0	+0.1	0.0	+0.1
CAFFEINE	0.0	0.0	0.0	0.0
ACACIA	0.0	0.0	0.0	0.0
FASTIN	+1.0	0.0	+1.0	+1.0

**Table 12B: Mean changes in Depression from baseline**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	+0.1	0.0	+0.1
CAFFEINE	0.0	0.0	0.0
ACACIA	0.0	+0.1	+0.5
FASTIN	0.0	+0.1	+0.1

**Figure 12: Changes in Depression from baseline**



**Anger** absolute scores are shown in Table 13A and the change in Depression scores from baseline are provided in Table 13B and Figure 13. There were no significant differences detected in Anger scores between FastinR-XR and any of the other three study conditions at any of the three time points examined.

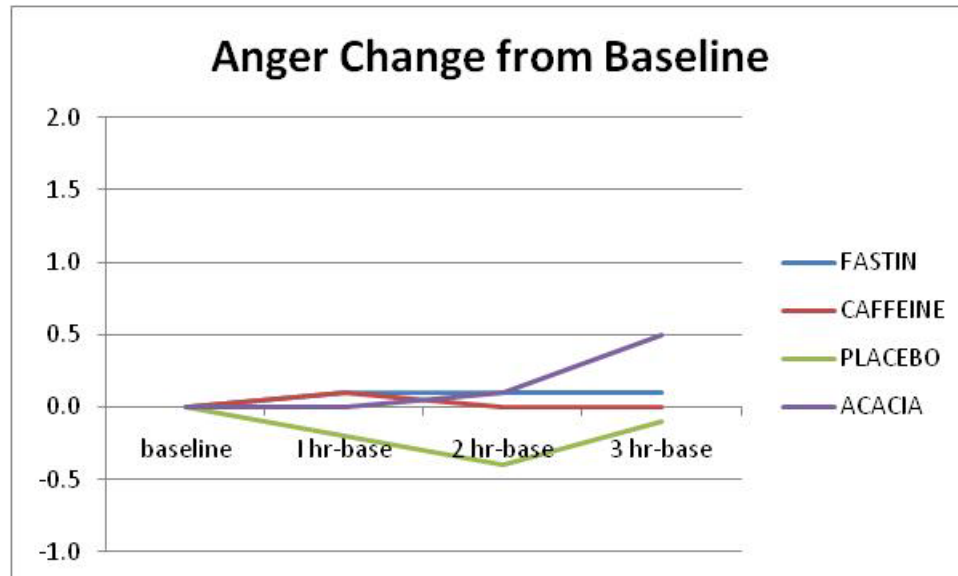
**Table 13A: Mean values of Anger**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	+0.4	+0.2	0.0	+0.3
CAFFEINE	0.0	+0.1	0.0	0.0
ACACIA	0.0	0.0	+0.1	+0.5
FASTIN	+0.1	+0.2	+0.2	+0.2

**Table 13B: Mean changes in Anger from baseline (ml/min)**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	-0.2	-0.4	-0.1
CAFFEINE	+0.1	0.0	0.0
ACACIA	0.0	+0.1	+0.5
FASTIN	+0.1	+0.1	+0.1

**Figure 13: Changes in Anger from baseline**



**Fatigue** absolute scores are shown in Table 14A and the change in Depression scores from baseline are provided in Table 14B and Figure 14. There were no significant differences detected between FastinR-XR and any of the other three study conditions at any of the three time points examined.

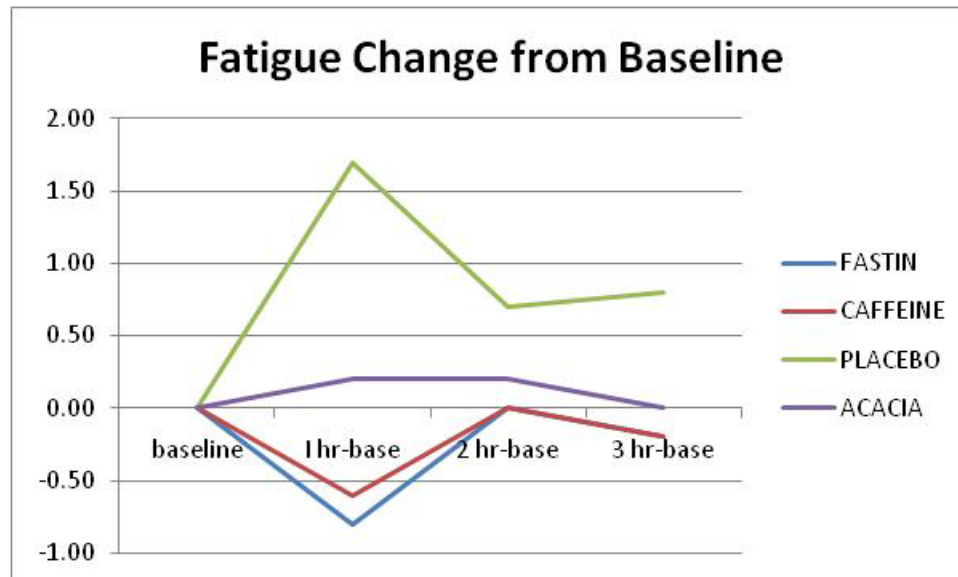
**Table 14A: Mean values of FATIGUE**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	+0.5	+2.2	+1.2	+1.3
CAFFEINE	+1.0	+0.4	+1.0	+0.8
ACACIA	+0.6	+0.8	+0.8	+0.6
FASTIN	+1.1	+0.3	+1.1	+0.9

**Table 14B: Mean changes in FATIGUE from baseline (ml/min)**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	+1.7	+0.7	+0.8
CAFFEINE	-0.6	0.0	-0.2
ACACIA	+0.2	+0.2	0.0
FASTIN	-0.8	0.0	-0.2

**Figure 14: Changes in Fatigue from baseline**





**Confusion** absolute scores are shown in Table 15A and mean changes from baseline are provided in Table 15B and Figure 15. Preliminary analyses revealed no significant differences between conditions at baseline ( $p>0.05$ ). Values of Confusion for Fastin<sup>R</sup>-XR were significantly greater ( $p>0.05$ ) than Placebo and Caffeine at 2hrs and 3hrs post ingestion. The Fastin<sup>R</sup>-XR Confusion scores were significantly greater ( $p>0.05$ ) than Acacia at 1hr, 2hrs and 3hrs post.

**Table 15A: Mean values of CONFUSION**

	<u>Baseline</u>	<u>1hr post</u>	<u>2hrs post</u>	<u>3hrs post</u>
PLACEBO	+0.8	+0.7	+0.6	+0.7
CAFFEINE	+0.8	+0.9	+0.7	+0.6
ACACIA	+0.4	+0.8	+0.5	+0.5
FASTIN	+0.3	+1.8	+1.5	+1.3

**Table 15B: Mean changes in CONFUSION from baseline (ml/min)**

	<u>Baseline to 1hr post</u>	<u>Baseline to 2hrs post</u>	<u>Baseline to 3hrs post</u>
PLACEBO	-0.1	-0.2	-0.1
CAFFEINE	+0.1	-0.1	-0.2
ACACIA	+0.4	+0.1	+0.1
FASTIN	+1.5	+1.2	+1.0

**Figure 15: Changes in Confusion from Baseline**

