Acute Effects of an Investigational Pre-Workout Supplement on Mood and Safety in Resistance Trained Males: A Proof-of-Concept, Randomized, Controlled, Crossover Study

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Introduction

Caffeine-containing multi-ingredient pre-workout supplements (MIPS), marketed as improving physical performance acutely, are a particularly popular category within sports nutrition and yet finished products are rarely clinically evaluated.

PURPOSE: The purpose of this randomized, controlled, crossover study was to examine the acute effects of an investigational MIPS formula when used by experienced resistance trained consumers of high-stimulant MIPS.

Methods

Healthy, resistance-trained, high-caffeine consuming (>200 mg/d), adult male, US military veterans were recruited to complete familiarization and 2 randomly assigned and counter-balanced lab visits to assess the acute effects of 16 fl ozs H2O (CTL; positive control) or H20+MIPS (C4A;C4® Alpha Bomb; Nutrabolt; Austin, TX).

ADVERSE EVENTS (AEs): At the end of each treatment (TRx) testing visit, participants completed an AE questionnaire that included a list of 9 AEs and an "Other" field. Participants answered "YES" or "NO" if, during the visit, they experienced or were experiencing each of the AEs listed. For all "YES" responses, the participant was instructed to indicate how likely – "Possible", "Likely", or "Very Likely" – they believed the AE effects were due to the TRx consumed.

CARDIOVASCULAR SAFETY: During TRx testing visits, subjects were assessed for resting heartrate (HR), blood pressure (SBP & DBP), and rate pressure product (RPP = HR x SBP) after a 5-min seated rest, prior to (PreTRx) and ~50 mins after (PostTRx) consuming TRx. Hemodynamic response was also assessed immediately after completion of maximal effort exercise testing (PostEX). Testing was performed using an automatic, upper-arm, electronic sphygmomanometer (OMRON Professional IntelliSense® Blood Pressure Monitor, HEM-907XL; Omron Healthcare: Lake Forest, IL, USA).

PROFILE OF MOOD STATES (POMS): POMS testing to assess transient affective state[1] occurred immediately prior to (PreTRx) and ~60 mins after (PostTRx) consuming the TRx. Age (adult), gender (male), and time ("right now") normative adjusted T-scores were determined for: Total Mood Disturbance (TMD), Anger-Hostility (AH), Confusion-Bewilderment (CB), Depression-Dejection (DD), Fatigue-Inertia (FA), Tension-Anxiety (TA), Vigor-Activity (VA), and Friendliness (F). TMD = (AH + CB + DD + FI + TA) – VA.[2] For example, TMD T-scores >50 suggest greater than normative average negative mood state; a significant (p<0.05) increase in TMD T-score suggests an increase in negative mood state; and, a significant (p<0.05) decrease in TMD T-score suggests a decrease in negative mood state / increase in positive mood state.

STATISTICAL ANALYSIS: Separate within-within 2x2 (TRx x time) repeated measures ANOVAs were used to compare the effect of each TRx over time, for hemodynamic and POMS. Multiple comparisons were performed using Fisher's LSD tests. AEs were compared between TRx using Wilcoxon matched-pairs signed rank tests for each variable. *Alpha* ≤ 0.05.

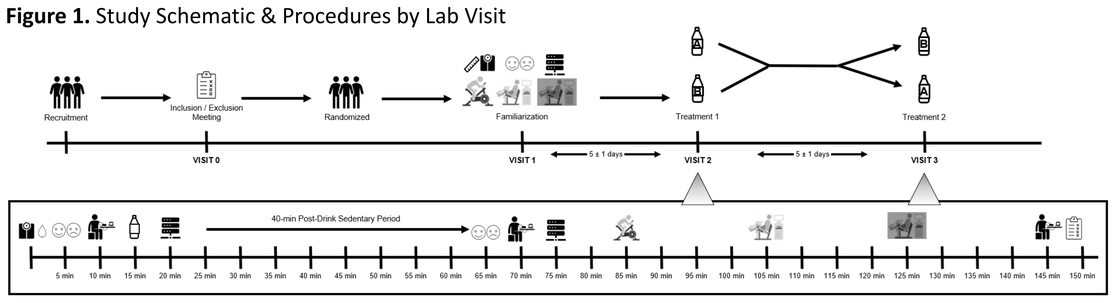
Table 1. Subject Characteristics (n=18)

	MEAN	SEM (±)	95% CI (±)
AGE (*yrs*)	40.6	1.7	3.4
BODYMASS (*kg*)	90.2	2.2	4.4
BMI (*kg/m²*)	28.7	0.6	1.1
CAFFEINE EXPECTANCY (B-CaffEQ)			
Withdrawal - Dependence (*0-15*)	5.8	0.7	1.5
Energy - Work Enhancement (*0-15*)	11.0	0.5	0.9
Appetite Suppression (*0-15*)	5.6	0.5	1.1
Social - Mood Enhancement (*0-15*)	8.0	0.5	1.1
Physical Performance Enhancement (*0-15*)	10.8	0.6	1.2
Anxiety - Negative Physical Effects (*0-15*)	4.6	0.5	1.0
Sleep Disturbances (*0-10*)	4.9	0.4	0.7

Table 2. Study Procedures by Lab Visit

PROCEDURES	VISIT 0	1	2	3
Pre-Qualification Questionnaire	x			
Caffeine Expectancy Questionnaire	x			
Inclusion/ Exclusion Meeting	x			
Informed Consent	x			
Familiarization		x		
Height		x		
Weight		x	x	x
24-Hr Pre-Test Controls (e.g., 5-7 hr Fast before Visit)			x	x
Hydration Status (HyDEX)			x	x
Hemodynamic Safety (HR, BP, RPP)		x	x	x
Consume Treatment			x	x
40-min Post-Treatment Latent Period			x	x
Profile of Mood States Questionnaire (POMS-2)		x	x	x
Psychomotor Performance (Dynavision)		x	x	x
Repeated Sprint Testing (Cycle Ergometer)		x	x	x
Lower Body Maximal Strength Testing (Biodex)		x	x	x
Lower Body Muscular Endurance Testing (Biodex)		x	x	x
Adverse Events Questionnaire			x	x
Compensation				x

Figure 1. Study Schematic & Procedures by Lab Visit



Results

AEs: Beta-alanine induced paresthesia was observed in 61% of subjects in response to C4A vs CTL (p=0.001). No other significant differences (p≥0.25) were observed for AEs between conditions.

CARDIOVASCULAR SAFETY: PreTRx to PostTRx HR was unchanged (p>0.05) by C4A, and there were no differences (p>0.05) in HR between C4A vs CTL at PostTRx and PostEX. C4A increased PreTRx to PostTRx SBP and DBP by 8.3 ± 1.7 mmHg and 4.2 ± 1.7 mmHg, respectively, and these effects by time were significant (p<0.05) but within the 5-15 mmHg and 5-10 mmHg changes to SBP and DBP from caffeine alone.[3] C4A PostTRx and PostEX SBP were significantly (p<0.05) greater than CTL; however, there were no within-treatment time effects (p>0.05) for PostTRx to PostEX SBP for either condition. PostTRx to PostEX DBP was unchanged by CTL, whereas C4A promoted a PostTRx to PostEX decrease in DBP (-4.8%; p<0.05). No differences (p>0.05) were observed for RPP between C4A and CTL.

POMS: There were no within or between treatment differences (p>0.05) for TMD. C4A reduced fatigue (FA) and increased TA from PreTRx to PostTRx [FA: -6.2% (p=0.0119); TA: +14.3% (p=0.0052)] and when compared to CTL at PostTRx [FA: -13.6% (p=0.0190); TA: +16.7% (p=0.0118)].

Figure 2. Adverse Events (AEs)

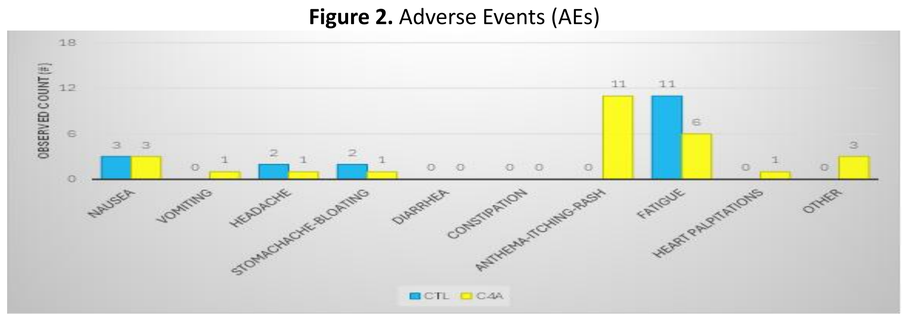


Figure 3. Cardiovascular Safety

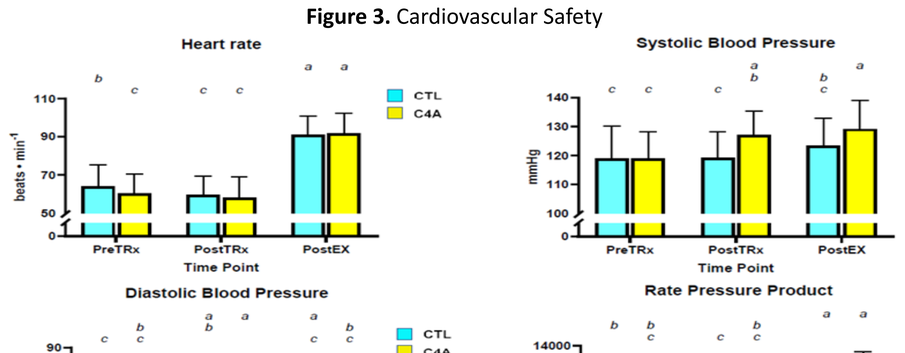
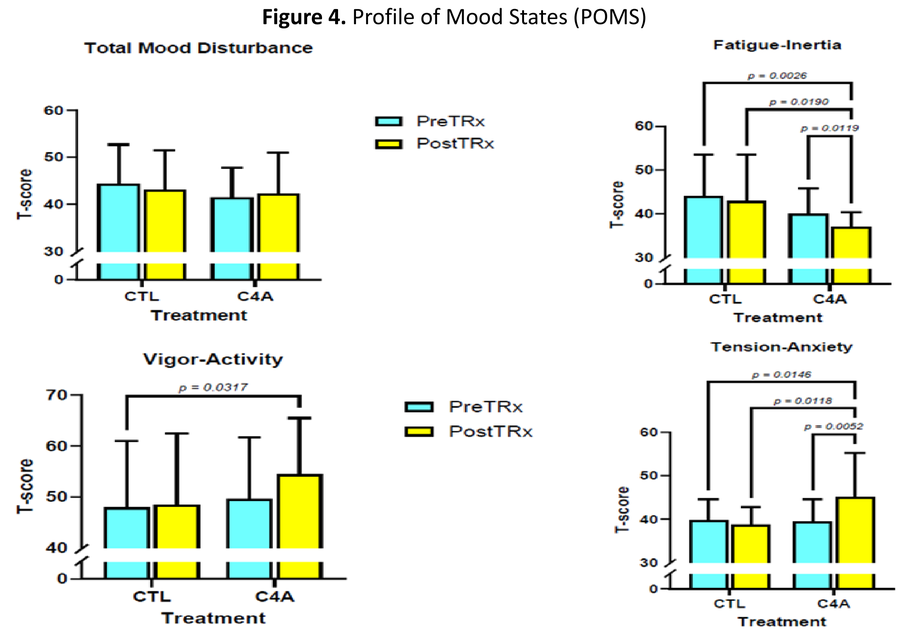


Figure 4. Profile of Mood States (POMS)



Conclusion

This pre-market proof of concept study suggests that acute use of C4A reduces fatigue (increases perceived energy) and increases feelings of anxiety or tension, but appears to pose no undue cardiovascular or safety risk when used by experienced resistance trainers that regularly consume caffeine-containing MIPS.

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References

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