# Capsaicinoids Reduce Appetite Response: An Open Label Study in Free Living Population

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# Abstract

The purpose of this study was to examine the effects of capsaicinoids (CAPs) supplementation for a week on resting heart rate, diastolic and systolic blood pressure, willingness to exercise, duration and intensity of exercise, and appetite. One-hundred and fifty two subjects (55 females and 97 males), aged 19 - 51 years old with a BMI of less than 40 kg/m<sup>2</sup> volunteered to participate. Written consent form for each subject was obtained prior to the participation in the study. The study lasted for seven consecutive day's intervention with supplementation for each subject; no placebos or washouts were included in this trial. Each subject was given 2 mg of CAPs capsule per day from proprietary Capsimax<sup>®</sup> and instructed to take with their breakfast meal. On Day 1, subjects completed their pre and general surveys on their lifestyle, appetite measures as well as testing for and recorded resting heart rate and blood pressure. On day 7, subjects completed the post survey questionnaires and recorded their resting heart rate and blood pressure. For pre and post analysis of resting Heart Rate and Blood Pressure (SBP and DBP), a paired-T test was used. Analysis of the pre/post supplementation surveys identified showed a significant decrease in appetite (-7.1%) as well as desire to exercise when comparing pre to post survey responses. There were no significant changes in heart rate and blood pressure after one week supplementation of CAPs. Subject's perceived body temperature increased during supplementation period. Subject responses showed an increase in workout intensity. Subject responses for their desire to snack changed to average desire (post supplementation) from highest level of desire prior to supplementation.

Keywords: Capsaicinoids; Appetite; Blood Pressure; Heart Rate; Exercise

# Introduction

Capsaicinoids are a group of chemicals with bioactive properties that are found in hot chili peppers. Nearly 100 studies have shown the benefits of capsaicinoids; including anti-inflammatory, antibacterial, and antioxidant properties, as well as an increase in energy expenditure, fat oxidation, and appetite control [1-3]. These results have increased interest and popularity of the chili peppers. Unfortunately for many individuals, consumption of these hot peppers triggers capsaicin receptors (transient receptor potential cationV1), which is a protein that responds to both heat and pain [4]. This reaction makes intake of chili peppers too hot for most to handle.

Capsaicinoids from capsicum extract, black pepper extract have been combined with other multi-ingredient supplements including caffeine which has shown an increase energy expenditure over the placebo by approximately 200 kcal [5]. The effects of a multi-ingredient supplement containing capsaicinoids (CAPs), raspberry ketones, caffeine, garlic, ginger and *Citrus aurantium* were tested on anthropometric variables in a study by Lopez., *et al* [6]. The capsaicinoids (CAPs) supplement significantly decreased circumference and body fat percentage compared to placebo [6].

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Capsicum fruit extract (Capsimax<sup>®</sup>) obtained from dried red fruits of *Capsicum annuum* L as a food ingredient. Capsimax<sup>®</sup> is a faint pinkish white colored free flowing uniform spheroidal beadlets with spicy odor characteristics of dried ripe fruits of capsicum. Capsaicinoids, such as capsaicin, dihydrocapsaicin, and nordihydrocapsaicin are the major pungent constituents of the capsicum fruit extract. Capsicum and its preparations have been commonly used as food for centuries, particularly in South America and Asian countries. The daily intake of chili peppers and the resulting approximate capsaicinoid exposure in Mexico, Korea, Thailand, India and the United States has been reported as are 15, 8, 5, 2.5, and 0.05-0.5 g chili pepper/person/day and 45, 24, 15, 7.5, and 0.15 - 1.5 mg capsaicinoid/person/ day, respectively. These values also show that the resulting daily intake of capsaicinoids (2 mg/person) from the intended uses Capsimax<sup>®</sup> is much smaller than the current background intake in several countries. Furthermore, the irritation potentials of capsaicinoids in Capsimax<sup>®</sup> are masked by a novel delivery technologies.

As we continue to explore the benefits of CAPs, further investigation was focused on the safety of supplementation specifically in freeliving individuals. The current open label study sought to explore if CAPs would have an effect on Heart Rate, Blood Pressure, and other variables. Therefore, the purpose of this study was to examine the effects of one week CAPs supplementation on resting heart rate, blood pressure, willingness to exercise, duration and intensity of exercise, and appetite.

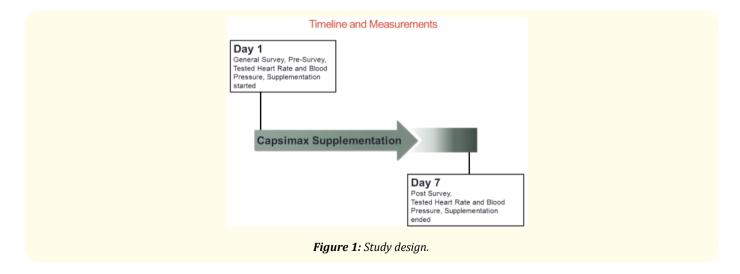
#### **Subjects and Methods**

#### Subjects

This is an open-label free living population acute intervention of capsaicinoids supplementation for 7 days to investigate its efficacy on appetite and other subjective responses to a questionnaire and its safety of use in 152 healthy volunteers. Inclusion criteria includes one-hundred and fifty two free living subjects (55 females and 97 males), aged 19 - 51 years old with a BMI of less than 40kg/m2, with a height of 177.39 + 7.95 cm volunteered to participate in this study. Written consent for each subject was obtained prior to the admission into the study. Exclusion criteria includes pregnancy/lactation; smokers, chronic disease/condition on prescriptions or supplements. Study was approved by an institutional review board (IRB number is 13-07 and was approved on June 10, 2015), The University of Tampa, FL. Study was registered at ISRCTN #16751129.

#### Methods

**Study design:** One hundred fifty two subjects were recruited. The study lasted for seven consecutive days with supplementation for each subject (Figure 1). It is an open label study hence no placebos or washouts were included in this trial (Table 1). Each subject was given 1 capsule (100 mg proprietary Capsimax<sup>®</sup> Capsicum Fruit Extract providing 2 mg capsaicinoids) of CAPs per day for 7 days and were instructed to take it with their breakfast meal.



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•	152 males and females, healthy subjects
•	Location: Tampa, Florida, USA
•	Subjects were free-living
•	Age= 19 - 51 years
•	$BMI = <40 \text{ kg/m}^2$
•	No chronic conditions, non-smokers
•	No pregnant and lactating women

Table 1: Subject Baseline Characteristics.

**Investigational product:** Capsimax capsules for the study were supplied by OmniActive Health Technologies Ltd, India. On Day 1, subjects completed their pre and general surveys (questionnaires) as well as testing for their resting heart rate and blood pressure using a blood pressure cuff on the left arm.

**Questionnaires:** Questionnaires were administered to each subject on Day 1 to Day 7 every day. The pre and post surveys asked questions that pertained to the subjects training level, energy, motivation, appetite, mood and perspiration. The post survey also includes questions regarding weight loss from the supplementation. The general survey consisted of questions pertaining to the subjects training, nutrition, and supplementation practices. On day 7, subjects completed the post survey (questionnaire), resting heart rate and blood pressure were assessed.

**Assessments:** Vital signs and anthropometric measurements were assessed and recorded. The BMI was calculated by dividing the body mass (kg) by the square of height (m). Blood pressure was measured using sphygmomanometer. Heart rate was also measured and recorded at baseline and at the end (Day 1 and Day 7).

## **Statistical Analysis**

Mean and standard deviations were calculated for all numerical measurements taken at pre and one week of study. Paired t-test analysis was then used to test for any differences in all measured variables with the significance level set at P < 0.05. For pre and post analysis of resting heart rate and blood pressure (SBP and DBP), a paired-T test was used. Histograms were used to simply demonstrate the distribution of the percent of total frequency of the questions pre and post. A paired T test was conducted for appetite and for other measures of assessments based on survey questionnaires.

#### Results

No significant differences were observed in baseline characteristics. Subjects's were healthy free living population. Subjects response to each survey questionnaire pre and post supplementation analyzed by days distribution.

**Vital Signs:** Analysis of the pre/post supplementation surveys identified showed no significant change in heart rate, systolic blood pressure and diastolic blood pressure (Figure 2).

**Appetite:** Analysis of the pre/post supplementation surveys identified showed a significant decrease in appetite (-7.1%, Figure 3) as well as desire to exercise when comparing pre to post survey responses. Although the duration of the study was short and lacked a placebo condition, this appetite suppression may be beneficial for long term weight control.

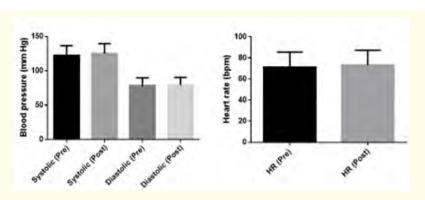
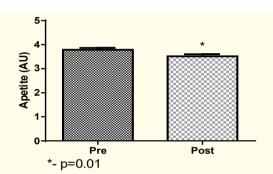


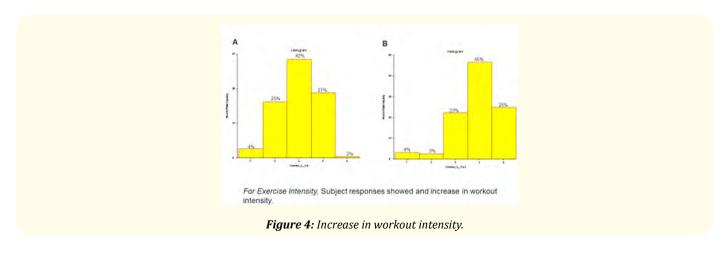
Figure 2: No Significant Change in Heart Rate and Blood Pressure.



**Figure 3:** Capsaicinoids Reduced Appetite in Post Treatment. For Appetite, There was a reduction (-7.1%) from pre-to post-assessment.

**Work Intensity and Other Responses:** Subjects perceived a body temperature increase during supplementation period. Subject responses showed an increase in workout intensity (Figure 4). Subject responses for their wish to snack changed to average (post supplementation). These results suggest effectiveness of the CAPs on the weight loss process. The more intense or longer the activity, the more calories burn for weight management.

Questions pertaining to mood, perceived body temperature, perspiration, and energy levels did not show any statistical significance from pre to post- test evaluation.



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#### Discussion

Capsaicinoids are also known to stimulate energy expenditure through activation of the sympathetic nervous system, which induces catecholamine [e.g., adrenaline] secretion from the adrenal medulla [7-10]. This thermogenic effect has been exploited for purposes of weight management. Capsaicinoids have been reported to reduce appetite [3,11,12], to increase thermogenesis [2,13-15], and to increase lipolysis, as measured by indirect calorimetry [2,13,14,16], or by serum glycerol and free fatty acids [1]. The science supports an association between capsaicinoid-containing food consumption and a lower incidence of obesity [7,17].

In the current study, analysis of the pre/post supplementation surveys identified showed a significant decrease in appetite (-7.1%) as well as want to exercise when comparing pre to post survey responses. King., *et al.* [18] suggest that exercise is useful for improving body composition and health. For example, when exercise-induced mean weight loss is < 1.0 kg, significant improvements in aerobic capacity (+6.3 ml/kg/min), systolic (-6.00 mm Hg) and diastolic (-3.9 mm Hg) blood pressure, waist circumference (-3.7 cm) and positive mood still occur. Adding capsaicinoids to exercise may further attenuate weight management process.

Appetite control is a complex phenomenon. Physiological and environmental factors contribute to appetite and eating behavior and are influenced by social and environmental factors. It is well established that the hypothalamic region of the brain plays a key role in the central regulation of eating behavior in humans. The hypothalamus, in particular the arcuate nucleus, is constantly receiving and processing neural, metabolic and endocrine signals from the periphery, enabling it to maintain energy homoeostasis [19]. In an acute study, fifteen minutes after lunch CAPS lunch increased GLP-1 (p < 0.05) and tended to decrease ghrelin (p = 0.07) as compared to the control lunch [20]. Recently, Tremblay., *et al.* [21] reported that CAPs stimulates the sympatho-adrenal system that mediates the thermogenic and anorexigenic effects of capsaicinoids. Capsaicinoids have been found to accentuate the impact of caloric restriction on body weight loss, increase energy expenditure, attenuates or even prevents the increase in hunger and decrease in fullness as well as the decrease in energy expenditure and fat oxidation, which normally result from energy restriction.

Interestingly, exercise studies alone had no significant effect on hunger, appetite and food consumption sensations. Stubbs., *et al.* [22,23] in two studies reported in normal weight individuals (both men and women), a 7-day exercise programme (80 or 120 min per day), with *ad libitum* food intake, did not induce any significant changes in subjective feelings of hunger or fullness (assessed hourly during waking hours) compared with a control condition. In another study [24] in normal and overweight male adolescents also failed to show any significant changes in the sensations of hunger, desire to eat or prospective food consumption, either in fasting or post-prandial, after 5 days of supervised aerobic exercise, despite a tendency towards a decrease in fullness (P = 0.055), in both the normal weight and overweight groups. In the current study, subject responses showed an increase in workout intensity. Exercise intensity must generally be at a moderate or vigorous level for maximum benefit of weight management.

Questions pertaining to mood, perceived body temperature, perspiration, and energy levels had no statistical significance from pre to posttest evaluation but a substantial increase in all physiological markers on 3rd day of supplementation compared to pre supplementation period. There are methodological limitations in the study, it is an open label free living population study and no placebo comparison. Hence further studies are required for long term effects of CAPs.

#### Conclusions

Our data suggest that ingestion of CAPs supplement may be beneficial in decreasing measures of appetite, reduction in their wish to snack, change in workout intensity which can support weight management. In addition, no change in HR, SBP, or DBP was noted after supplementation. Future studies should examine the long term effects of CAPs supplementation on appetite, weight loss, and body composition using a randomized, double blind, placebo controlled trial.

#### Acknowledgement

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# **Conflict of Interest**

Authors are employees of OmniActive Health Technologies, Inc., NJ.

# **Study Funding**

OmniActive Health Technologies Ltd. India.

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