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Capsaicinoids supplementation effect on appetite and body composition in healthy men and women

Submission date
13/04/2016

Recruitment status
No longer recruiting

Registration date
20/04/2016

Overall study status
Completed

Last Edited
21/08/2018

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
There is evidence to suggest that capsaicinoids (CAP), substances found in the white pulp of chili peppers that gives them “heat” may have a number of health benefits, including helping weight loss and having anti-inflammatory and antioxidant effects. Studies have shown that CAP may help people to lose weight by, for example, stopping so many calories from being absorbed in the gut, reducing body fat and increasing metabolism. The aim of this study is to see whether taking a capsaicin supplement can affect a person’s appetite and body size a period of 12 weeks, comparing the effects of two different doses.

Who can participate?
Healthy adults aged between 18-56 and with a BMI of between 24.5-29.5 kg/m

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 are given 2mg CAP to take for 12 weeks. Those in group 2 are given 4mg CAP to take over 12 weeks. Those in group 3 are given a placebo (dummy) pill to take over 12 weeks. All participants are asked not to make any changes to their current levels of physical activity, restrict their intake of spicy foods and maintain their usual caloric intake from their diet. Each participants appetite and energy (food) intake, body measurements, BMI, glucose, insulin and fat levels and also their quality of life is assessed at the start of the study and again at the end.

What are the possible benefits and risks of participating?
This study may help participants to learn about their appetite and metabolic health and how they may be affected by taking capsaicinoids. This study may help them to understand how taking capsaicinoid supplements can be useful for weight management. There is no risk in taking part in the study.

Where is the study run from?
University of Mary Hardin-Baylor (USA)

When is the study starting and how long is it expected to run for?
June 2015 to December 2015

Who is funding the study?
OmniActive Health Technologies Ltd

Who is the main contact?
Dr Vijaya Juturu

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
UMHB_OAHT009

Study information

Scientific Title
Capsaicinoids supplementation reduces appetite and body circumferences in healthy men and women: a placebo controlled randomized double blind study

Study objectives
Consumption of capsaicinoids (CAP), the bioactive and pungent principles in red hot pepper, has been shown to increase energy expenditure and may impact overall metabolism. In vivo studies suggest that supplementation of CAP could positively affect risk factors of cardiovascular health. Therefore, the purpose of this study was to examine the effects of two different doses of CAP on appetite and body circumference in healthy men and women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional Review Board (IRB) at the University of Mary Hardin-Baylor, 09/05/2015

Study design
Double blind randomized placebo controlled design

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Affects of of consumption of capsaicinoids

Interventions
In a double blind, randomized, placebo controlled design seventy-seven (29.6 ± 11.3 y, 171.2 ± 9.8 cm, 80.9 ± 18.9 kg, 27.4 ± 5.4 kg/m2) apparently healthy males and females were randomly assigned by fat mass to ingest either CAP (2mg CAP, CX1 or 4mg CAP, CX2 [CX, Capsimax®, OmniActive Health Technologies Ltd.]) or placebo (corn starch, PLA) for 12 weeks. Subjects were requested not to make any changes to their current physical activity, provided instructions to restrict spicy foods and maintain current caloric intake. Subjects were instructed to take the pills with 8 ounces of water after breakfast. At baseline (T1), 6 weeks (T2) and 12 weeks (T3), waist and hip circumferences, waist: hip ratio (WC, HC, and WHR), weight, appetite levels via Council on Nutrition appetite questionnaire (CNAQ) and adverse events questionnaires were administered. At baseline (T1) and 12 weeks (T3) complete blood count and complete metabolic panels were assessed. Statistical analyses utilized a two-way ANOVA (group x time) with repeated measures for all dependent variables ($p < 0.05$).

Intervention Type
Supplement

Primary outcome measure
1. Appetite and energy intake will be measured based on CNAQ and dietary intakes at baseline and at week 12
2. Body indices such as waist and hip circumference, measured at baseline and week 12
3. WHR and BMI, measured at measured at baseline and week 12

4. Body composition using DEXA, measured at baseline and week 12
5. Glucose, insulin and lipid profile, measured at baseline and week 12

Secondary outcome measures
Quality of life (QoL), assessed using SF 36 Questionnaires at baseline and week 12

Overall study start date
15/06/2015

Completion date
30/12/2015

Eligibility

Key inclusion criteria
1. Willing to sign informed consent form
2. Male and Females aged 18-56 years, normal healthy individuals
3. BMI of 24.5-29.5 kg/m
4. Participant has not used any ergogenic aids within the previous 6 months of the start of the study
5. Participant is willing and able to comply with protocol
6. Participant is apparently healthy and free from disease, as determined by a health history questionnaire
7. Participant agrees to abstain from strenuous activity 24-48 hours prior to each testing visit
8. Participant agrees to be fasted for 12 hours prior to each testing visit
9. Participant agrees to refrain from smoking, caffeine, and tobacco for 12-hours prior to each testing visit
10. Participant agrees to abstain from consuming alcohol 24-hours before each testing visit
11. Participant has provided written and dated informed consent to participate in the study
12. Participant is currently not pregnant or does not plan to become pregnant during the duration of the study

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
56 Years

Sex
Both

Target number of participants
40

Key exclusion criteria

1. Women who are pregnant, lactating within 6 weeks before the study start and during study, or planning to become pregnant 3 months before or during the study
2. Post menopausal women on hormone replacement therapy (HRT) for less than 90 days prior to randomization
3. Uncontrolled hypertension as defined by a blood pressure of 150/90 on two or more occasions or use of antihypertensive medications which may affect energy expenditure including alpha blockers, beta blockers, angiotensin receptor blockers or inhibitors of angiotensin converting enzyme
4. Current use of tobacco products, marijuana, amphetamines, cocaine or intravenous drug use
5. Chronic ethanol use (> 3 drinks /day)
6. Endocrine disorders including hypo or hyperthyroidism (including subclinical disease), Cushings disease, growth hormone deficiency or other pituitary diseases
7. Chronic renal impairments (serum creatinine 180 mmol/liter), active liver disease;
8. Moderate to severe peripheral vascular disease
9. Severe chronic obstructive pulmonary disease, congestive heart failure (New York Heart Association 2), angina requiring nitrates
10. Use of other medications to treat obesity including medications obtained over the counter or internet, orlistat (Xenical, Alli), sibutramine (Meridia), or phentermine (Adipex P) within the past 6 months
11. History of an eating disorder including anorexia or bulimia
12. History of surgery for the treatment of obesity (gastric banding, gastric bypass)
13. Diagnosis of type 1 or type 2 diabetes mellitus according to American Diabetes Association guidelines
14. Have any known metabolic disorder including heart disease, arrhythmias, diabetes, thyroid disease, or hypogonadism
15. Have taken ergogenic levels of nutritional supplements that may affect muscle mass or aerobic
capacity (e.g., creatine, HMB) or anabolic/catabolic hormone levels (e.g., androstenedione, DHEA, etc.) within 6 months prior to the start of the study
16. Have any absolute or relative contraindication for exercise testing or prescription as outlined by
the American College of Sports Medicine
17. Report any unusual adverse events associated with this study that in consultation with the supervising physician recommends removal from the study
18. Have consumed any dietary supplements (excluding multivitamins, including herbal supplements for weight loss, or any other metabolic condition) 1 month prior to the study;
19. Have completed participation in any other clinical trial during the past 6 months;
20. Have a strong history of food or drug allergy of any kind
21. Any other condition in which principal investigator thinks may jeopardize the study;
22. Taking any satiety, diet or sport shake, powder or drink
23. Use of systemic corticosteroids such as oral/injectable hydrocortisonestable maintenance or low dose for >12 weeks
24. Use of statins (or any other medication for the treatment of hypercholesterolemia) such as atrovastatin (Lipitor), rosuvastatin (Crestor), simvastatin (Zocor), gemfibrozil (Lopid), etc
25. Any weight loss regimens, and intake of cholesterol lowering supplements such as fish oil capsules, phytoestrogens, soy lecithin or any polyphenols
26. Use of prescription antacids or anti-inflammatory medications on a regular basis. If acute intake, medication should not be used with 1 week of the test day
27. Use of drugs acting on the gut such as ezetimibe (Zetia), bile-acid binding resins and orlistat (Xenical)

28. Immunocompromised individuals such as subjects that have undergone organ transplantation or subjects diagnosed with human immunodeficiency virus (HIV) and treatment related infectious diseases or disorders
29. History of hemoglobinopathies such as sickle cell anemia or thalassemia, sideroblastic anemia;
30. Use of natural health products other than products containing vitamins or minerals as the sole medicinal except vitamin E or niacin (vitamin B3), 4 weeks prior to randomization and during the course of the trial
31. Past cardiac surgery or any surgical treatments for chronic diseases or planned surgery during the trial
32. History of diabetes, stroke, cardiovascular disease, cancer (except for successfully treated basal cell skin cancer, in situ carcinoma of the cervix, or in situ prostate cancer), myocardial infarction, mental health disorders, GI disorders and infectious diseases
33. Uncontrolled hypertension defined as SBP ≥ 140 mmHg and/or DBP ≥ 90 mmHg with or without treatment
34. Alcohol consumption > 2 standard alcoholic drinks per day
35. Red wine consumption except when subject agrees to refrain during the study period
36. Current (or history of) significant confounding illness, allergy, substance abuse or condition that would prohibit participation
37. Allergy or sensitivity to study supplement ingredients
38. Spices in diets – please list products to avoid during study period or limit
39. Individuals who are cognitively impaired and/or who are unable to give informed consent
40. Any other condition which in the Investigator's opinion may adversely affect the subject's ability to complete the study or its measures or which may pose significant risk to the subject
41. Use of any dietary supplement for weight loss or weight management
42. Avoid capsiate /capsaicin/capsaicinoid supplements during the period of study
43. Minimize intake of hot chilli or hot peppers from different cuisines from Asia, China and Mexico, sauces, condiments, meals, pickles etc. [Specify sources of intake and record the data]. If possible avoid during the study period
44. Minimize spices and condiments such as black pepper, ginger, mustard etc. (record all sources and intake)
45. Use of prescriptions for weight management and weight loss
46. Use of diets for weight regimen or weight loss or weight management
47. No change in their daily activities

Date of first enrolment
20/06/2015

Date of final enrolment
30/07/2015

Locations

Countries of recruitment
United States of America

Study participating centre
University of Mary Hardin-Baylor
900 College St, Belton
TX 76513
United States of America
76513

Sponsor information

Organisation
OmniActive Health Technologies Inc

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Sponsor type
Industry

ROR
https://ror.org/024e1pj18

Funder(s)

Funder type
Industry

Funder Name
OmniActive Health Technologies

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

Results and Publications

Publication and dissemination plan

Intention to publish date
30/12/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2017		Yes	No
Results article	results	13/08/2018		Yes	No