

# Acute effects of capsaicin.

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Red pepper might prevent reduction of energy expenditure and elevation of hunger as a result of energy intake restriction.

<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON29649

### Bron

Nationaal Trial Register

### Verkorte titel

CAPS

### Aandoening

Obesitas, overgewicht

## Ondersteuning

**Primaire sponsor:** McCormick and Maastricht University

**Overige ondersteuning:** McCormick

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

The primary endpoint of this study is the change in 36h energy expenditure.

# Toelichting onderzoek

## Achtergrond van het onderzoek

### Rationale:

Red pepper might prevent reduction of energy expenditure and elevation of hunger as a result of energy intake restriction.

### Objective:

To investigate the acute effects of capsaicin on energy expenditure, substrate oxidation, appetite profile and ad libitum energy intake during negative energy balance.

### Study design:

The study will be conducted in a crossover design with four randomly sequenced conditions. Energy expenditure and substrate oxidation will be continuously monitored for 36h. Appetite profile will be measured hourly. Ad libitum energy intake will be measured during the last meal.

### Study population:

Sixteen healthy subjects (8 males and 8 females) with BMI between 20-30 kg/m<sup>2</sup> and aged between 18-50 years will be included in the study. All subjects will be non-smoking, weight stable, dietary unrestrained, and at most moderate alcohol and caffeine consumers. Subject will be free of medication except for oral contraceptives use in women.

### Intervention:

Subjects will stay for each of the four conditions in a respiration chamber for 36h, twice receiving an energy-balanced (100 En%) diet and twice an energy-restricted (75 En%) diet, both with and without added capsaicin (100%control, 75%control, 100%CAPS, 75%CAPS). An ad libitum meal will be served at the end of the second day.

### Main study parameters/endpoints:

Energy expenditure, substrate oxidation, appetite profile and ad libitum energy intake.

## **Doel van het onderzoek**

Red pepper might prevent reduction of energy expenditure and elevation of hunger as a result of energy intake restriction.

## **Onderzoeksopzet**

Subjects spent 4 x 36 hrs in the respiration chamber. Each hour between 07.00 AM and 11.00 PM they have to fill in several questionnaires. Furthermore their urine will be collected every 12 hrs for analysis of nitrogen.

## **Onderzoeksproduct en/of interventie**

Subjects will stay for four conditions in a respiration chamber for 36h, twice receiving an energy-balanced (100 En%) diet and twice an energy-restricted (75 En%) diet, both with and without added capsaicin (100%Control, 75%Control, 100%CAPS, 75%CAPS). The four test sessions will be conducted four weeks apart to prevent possible treatment-induced effects and to take eventual effects of menstrual cycle phase on energy intake and energy expenditure in women into account.

Two days prior to each test session subjects will be provided with a diet at home, in energy balance and with the same macronutrient composition as they will receive during the test sessions. On each of the four test days subjects arrive at the University after an overnight fast at 8:00h, whereafter they enter the respiration chamber at 8:30h. Energy expenditure, substrate oxidation and activity level will be continuously measured from 8:30h to 20:30h on the next day. Breakfast will be provided at 8:30h and at 13:30h subjects will receive lunch, followed by dinner at 18:30h. As part of each meal subjects will consume tomato juice (100%Control, 75%Control conditions) or tomato juice with added capsaicin (100%CAPS, 75%CAPS conditions). Subjects will be instructed to go to sleep around 23:30h. The next morning, subjects will be waked at 7:30h. Thereafter, the same protocol as during the previous day will be followed, until dinner. At 18:30h the subjects will receive an ad libitum meal.

Appetite profile will be measured using anchored 100-mm visual analogue scales (VAS). These questionnaires will be completed every waking hour, and before and after every meal on feelings of hunger, fullness, appetite, satiety, thirst, prospective food consumption, and desire to eat.

Urine samples are collected from the second void on the day subjects enter the respiration chamber to 20:30h on the next day. A total of 3 samples will be collected in containers in

order to determine the substrate oxidation.

## Contactpersonen

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

A total of 16 subjects (8 males and 8 females) with BMI 20-30 kg/m<sup>2</sup> and aged between 18-50 years will be included in the study. All subjects will be healthy, non-smoking, not using a more than moderate amount of alcohol (> 10 consumptions/wk) or caffeine-containing beverages (> 2 cups/d), being weight stable (weight change < 3kg during the last 6 months), dietary unrestrained and not using medication or supplements except for oral contraceptives in women.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Subjects will be excluded if they are not healthy, smoking, using a more than moderate amount of alcohol or caffeine-containing beverages, not being weight stable, dietary restraint, using medication or supplements except for oral contraceptives in women, or if they do not meet the criteria for BMI and age. Pregnant and lactating women, and subjects with allergies for the used food items will also be excluded from participation.

## Onderzoeksopzet

### Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

### Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-07-2011
Aantal proefpersonen:	16
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	20-06-2011
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

Register	ID
NTR-new	NL2803
NTR-old	NTR2944
Ander register	METC azM/UM : 11-3-005
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Resultaten

### Samenvatting resultaten

N/A