

# The effect of two dosages of theobromine and caffeine on mood and cognition in healthy subjects

Published: 08-04-2009

Last updated: 05-05-2024

To investigate the effect of two different dosages of theobromine and caffeine (450 mg theobromine and 60 mg caffeine and 300 mg theobromine and 40 mg caffeine respectively) and placebo on mood and cognition in healthy subjects.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33090

### Source

ToetsingOnline

### Brief title

08063V theobromine and caffeine

### Condition

- Other condition

### Synonym

NAP

### Health condition

stemming en cognitie

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Unilever

**Source(s) of monetary or material Support:** Unilever financiert eigen onderzoek

## Intervention

**Keyword:** caffeine, cognition, mood, theobromine

## Outcome measures

### Primary outcome

Explicit and implicit mood

Concentration and attention

### Secondary outcome

Blood pressure

Personality scores

## Study description

### Background summary

Theobromine and caffeine are both stimulants. Theobromine is less potent, but it also causes less negative side effects, like headaches and jitteriness.

A previous Unilever study compared the effects from caffeine and theobromine alone as well as a combination of both on mood and cognition. Caffeine and theobromine combined resulted in positive mood effects as well as increased task engagement.

This previous study was a proof-of-principle study with high doses of ingredients. The current study will use smaller doses closer to what is found in a serving of dark chocolate. Only combinations of theobromine and caffeine will be tested. In addition, the test battery differs from the one that has been used before.

### Study objective

To investigate the effect of two different dosages of theobromine and caffeine (450 mg theobromine and 60 mg caffeine and 300 mg theobromine and 40 mg

caffeine respectively) and placebo on mood and cognition in healthy subjects.

## **Study design**

Study has a doubleblind, randomized, cross-over design. Duration is 3 weeks with a one-week wash-out in between measurement days.

Each subject will consume all three testproducts in a random order: (1) combination of theobromine (450 mg) and caffeine (60 mg), (2) theobromine (300 mg) and caffeine (40 mg) and (3) placebo. Each condition consists of 4 capsules. Capsules will be consumed with 250 ml of water.

There will be three measurement days, on which subjects need to be present at the consumer center. On each measurement day they will take one of the treatments, fill in several questionnaires, and perform several computer tests. In addition, blood pressure will be measured twice (see E4).

## **Intervention**

3 different conditions

1. Placebo: 4 x capsules filled with Avicel PH-101, Ph Eur (Fluka)
2. High theobromine (450 mg) and caffeine (60 mg): 3 x capsule with theobromine (150 mg) + 1 x capsule with caffeine (60 mg)
3. Low theobromine (300 mg) and caffeine (40 mg): 2 x capsule with theobromine (150 mg) + 1 x capsule with caffeine (40 mg) + 1 placebo capsule.

All capsules are filled to the same volume so that all appear equal. The gelatin capsules (size 0 or 1) will be produced by Metagenics (Belgium).

## **Study burden and risks**

No medical or health risks are expected. However, subjects could report caffeine withdrawal effects.

## **Contacts**

### **Public**

Unilever

Olivier van Noortlaan 120  
3133 AT Vlaardingen  
Nederland

### **Scientific**

Unilever

Olivier van Noortlaan 120  
3133 AT Vlaardingen  
Nederland

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Age at start of the study  $\geq 18$  and  $\leq 55$  years

Being female

Body mass index (BMI)  $\geq 18.5$  and  $\leq 30.0$  kg/m<sup>2</sup>.

Reported alcohol consumption  $< 14$  alcohol units/week

Agreeing to be informed about medically relevant personal test-results

Informed consent signed

Willing to refrain from caffeine and theobromine for 28 hours, from 8 p.m. on the day prior to the measurement day until the end of the measurement day (0:00 - midnight)

Apparently healthy: no reported current or previous diseases or disorders which might effect study measurements assessed by Research physician

Consuming animal foods products (gelatine).

Consumes dark chocolate at least once in a month

Having a general practitioner (GP)

### Exclusion criteria

Being an Unilever employee

Consumes more than 250 mg caffeine daily

Using or planning to use any medically prescribed diet or weight-loss diet or making any attempt to control diet at screening and during the entire study.

Reported intense sporting activities  $> 10$  h/w

Subjects who undergoing medical treatment that may interfere with the study outcome.

Use of systemic antibiotics in the period of 3 months prior to the study

Reported participation in another biomedical study 1 month before the start or during the study.

Reported intolerance or allergy for one of test products or standardized meal

The habit of smoking during the past half year or using nicotine containing medicines during the past month

Reported lactating (or lactating < 6 weeks ago), pregnant (or pregnant < 3 months ago) or wish to become pregnant during the study

Office systolic blood pressure > 160 mmHg and/ or diastolic blood pressure > 95 mmHg, irregular heart rate and/or heart rate > 100 bpm. Eligibility of subjects with a heart rate <56 bpm will be assessed by the research physician

Not able to perform the computer tasks assessed during screening

Reported participation in night shift work during the study period

## Study design

### Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	09-04-2009
Enrollment:	28
Type:	Actual

## Ethics review

Approved WMO	
Date:	08-04-2009
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

### In other registers

Register	ID
CCMO	NL27096.081.09