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

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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.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	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 jitteryness.
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 befire.

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 >= 18 and <= 55 years
Being female
Body mass index (BMI) >= 18.5 and <= 30.0 kg/m2.
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