The effects of a combination of natural ingredients on cognition in healthy young volunteers

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Examine the effects of a treatment that consists of different natural ingredients on cognitive performance in young healthy subjects. These effects will be compared with caffeine treatment, a natural ingredient that has been found to improve…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON43125

Source
ToetsingOnline

Brief title
Natural ingredients and cognitie

Condition

- Other condition

Synonym
nvt

Health condition

geen aandoening

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Ministerie van OC&W,Het kleine bedrijf Nootrobox (1161 Mission Street San Francisco, CA geoff@nootrobox.com)

Intervention

Keyword: Cafeine, Cognition, Natural ingredient

Outcome measures

Primary outcome

The primary outcome measure is the number of recalled words in a verbal word

learning task.

Secondary outcome

The following secundary measures will be examined in this study:

* The number of words memorized long-term in a verbal learning task.

* De recognition of words in a verbal learning task.

* The number of correct responses in a working memory task.

* The performance on the Stroop to measure attention and inhibition.

* The performance on the Digit symbol substitution task to assess complex

scanning.

* The speeds of responding in combination with correct responses in a

psychomotor task.

Study description

Background summary

There is still a great need to find treatments that can improve cognitive function in old people that suffer from memory and attention problems. There

are various natural ingredients that have been claimed to improve cognitive functions in humans (e.g., caffeine, L-theanine, vinpocetine). These ingredients have a different mechanism of action and are assumed to have a general effect on brain function. It is hypothesized that a combination of these natural ingredients may be more effective to improve cognitive performance. In this study we would like to test the cognition-enhancing potential of a mixture of different natural ingredients.

Study objective

Examine the effects of a treatment that consists of different natural ingredients on cognitive performance in young healthy subjects. These effects will be compared with caffeine treatment, a natural ingredient that has been found to improve cognition in various studies.

Study design

This study will use a double-blind placebo controlled cross-over design.

Intervention

The subjects will be tested three times. At each test session they will receive one capsule (Placebo, Caffeine, or Combi).

Study burden and risks

The subjects who will be included in the study will visit the testing site four times (medical screening + practice session, and three test sessions). Each testing session will last 2.5 h. In total the subjects will spent about 10 h when they participate. During the three test sessions the subjects will receive a capsule that contains a placebo, caffeine or a combination of different natural ingredients. These treatments are well tolerated. No adverse reactions of treatment are expected. The subjects have to abstain from drinking coffee and smoking the evening before the test days.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18-35 years of age
Healthy
normal static binocular acuity (corrected or uncorrected)
willingness to sign informed consent

Exclusion criteria

history of cardiac, hepatic, renal, pulmonary, neurological, gastrointestinal, haematological or psychiatric illness, are excessive drinking (>20 glasses of alcohol containing beverages a week),
pregnancy or lactation, use of medication other than oral contraceptives, use of recreational drugs
from 2 weeks before until the end of the experiment, and any sensory or motor deficits which could
reasonably be expected to affect test performance. Those volunteers who have a first-degree relative with a psychiatric disorder or a history of a psychiatric disorder will also be excluded.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Double blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-10-2016
Enrollment:	21
Type:	Actual

Ethics review

Approved WMO

Date:	07-09-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL57694.068.16

Study results

Date completed:	21-07-2017
Actual enrolment:	21