The effects of a cognition enhancer (CILTEP) on a cognitive test battery and EEG in middle-aged and old volunteers

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To
examine the effects of a treatment that consists of different natural ingredients on cognitive performance in two different age groups. These effects will be compared with placebo treatment.

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

Summary

ID

NL-OMON47611

Source
ToetsingOnline

Brief title
CILTEP and cognition

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,Natural Stacks,Natural Stacks (16192 Coastal Highway, Lewes, DE 19958, Verenigde Staten)

Intervention

Keyword: Cognition, EEG, PDE 4-inhibitors

Outcome measures

Primary outcome

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

rning task, and the score on a spatial memory task which measures how

efficiently subjects can separate a representation of a picture from a similar,

but different, picture.

Secondary outcome

The following secundary measures will be examined in this study:

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

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

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

ng.

* The speed of responding in combination with correct responses in a psychomotor

task.

*The performance on a trail making test which measures mental flexibility and

attention.

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

* EEG measurement during the above mentioned behavioral tasks and during a

sensory gating task, which look at the efficiency of the brain in filtering out

unnecessary information.

Study description

Background summary

There is still a great need to find treatments that can improve cognitive functi
on in people that suffer from memory and
attention problems. There are various natural ingredients that have been claimed
 to improve cognitive functions in humans, such as PDE 4-inhibitors. In this
study, a PDE 4-inhibitor will be combined with an ingredient that can enhance
this PDE 4-inhibition, together with other natural ingredients which have
potential to improve cognition as well.
It is hypothesized that this combination of these natural ingredients may
be more effective to improve cognitive performance that PDE 4-inhibition
alone.

Study objective

To
examine the effects of a treatment that consists of different natural ingredient
s on cognitive performance in two different age
groups. These effects will be compared with placebo treatment.

Study design

This study will use a double blind placebo controlled crossover design.

Intervention

Participants will be tested two times. During each test session, they will
receive one capsule (CILTEP or placebo).

Study burden and risks

The subjects who will be included in the study will visit the testing site
three to four times (medical screening + practice session including memory
screening, and two test sessions). Each testing session will last 2.5 h and the
medical screening, training and memory screening maximum 3
h. In total the subjects will spend about 8 h when they
participate. During the two test sessions the subjects will receive a capsule th

at contains a placebo, or a
combination of different natural ingredients. These treatments are well tolerate
d. No adverse reactions of treatment are
expected. The subjects have to abstain from drinking coffee and alcohol. Two
blood samples will be taken on each test day.

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

30-40 or 60-75 years of age
Healthy
Normal static binocular acuity (corrected or uncorrected)
Body mass index between 18.5-30
Score op de Woord-Leertaak die binnen 1 standaarddeviatie van het gemiddelde valt

Willingness to sign informed consent

Exclusion criteria

having a history of cardiac, hepatic, renal, pulmonary, neurological, gastrointestinal, haematological or psychiatric illness, having a first-degree relative with a psychiatric disorder or a history with a psychiatric disorder, excessive drinking (>20 glasses of alcohol containing beverages a week), pregnancy or lactation, use of psychoactive medication, centrally acting beta blockers, use of recreational drugs from 2 weeks before until the end of the experiment, systolic blood pressure above 160 mmHg, phenylketonuria, any sensory or motor deficits which could reasonably be expected to affect test performance, and use of steroids or Sudafed (pseudoephedrine).

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):	03-07-2017
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO

Date:	01-06-2017
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

ID: 21957
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL60999.068.17
OMON	NL-OMON21957

Study results

Date completed:	30-11-2018
Actual enrolment:	91