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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21957

Source
Nationaal Trial Register

Brief title
CILTEP and cognition

Health condition

Long-term memory

Sponsors and support

Primary sponsor: Maastricht University, Department of Neuropsychology & Psychopharmacology
Source(s) of monetary or material Support: N/A

Intervention

Outcome measures

Primary outcome

To establish the effects of CILTEP on cognition, especially memory. The main cognitive tests that will be used are the verbal learning task (VLT), in which participants need to memorize

words that are presented on a screen, and the spatial pattern separation test, using photographs to assess episodic memory.

Secondary outcome

Performance in several other cognitive tests will be our secondary objective. We will examine the effects of CILTEP on working memory performance using an n-back task, on information processing speed using the digit symbol substitution test (DSST), on motor speed using a simple and choice reaction time task (SRT and CRT, respectively), on attention and concept shifting using the trail making test, and on response inhibition and focused attention using the Stroop. A sensory gating paradigm is included to examine the effect of our treatment on specific ERP components related to basic auditory processing.

Study description

Background summary

N/A

Study objective

- CILTEP can improve cognition in healthy volunteers, specifically memory

- The effects of CILTEP will be discernable in the ERP components measured: the P50, P300, N400, and P600 amplitudes are expected to be enlarged by CILTEP

Study design

N/A

Intervention

Volunteers will be tested on 2 separate days and will be administered either CILTEP or a placebo. Before inclusion, they will undergo a memory and a medical screening The order of treatment will be randomized.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male or female;

2. 30 to 40 or 60 to 75 years of age;

3. healthy (i.e. absence of all exclusion criteria);

4. body mass index between 18.5 and 30;

5. Verbal Learning Test screening score within the -1 and +1 standard deviation;

6. willingness to sign an informed consent.

Exclusion criteria

1. history of cardiac, hepatic, renal, pulmonary, neurological, gastrointestinal, haematological, or psychiatric ilness or a first-degree relative with a psychiatric disorder or a history with a psychiatric disorder;

2. excessive drinking (> 20 glasses of alcohol containing beverages a week);

3. pregnancy or lactation;

4. use of use of psychoactive medication or centrally acting beta blockers;

5. use of recreational drugs from 2 weeks before the experiment until the end of the study;

6. systolic blood pressure above 160 mmHg;

7. phenylketonuria;

8. any sensory or motor deficits which could reasonably be expected to affect test performance;

9. use of steroids or Sudafed (pseudoephedrine)

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-06-2017
Enrollment:	120
Type:	Actual

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	19-04-2017

Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47611
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6001
NTR-old	NTR6400
CCMO	NL60999.068.17
OMON	NL-OMON47611

Study results

Summary results
Pending