

# De FOCOM studie: een studie naar activatie van hersengebieden tijdens het maken van opdrachten op de computer

No registrations found.

|                              |                            |
|------------------------------|----------------------------|
| <b>Ethical review</b>        | Positive opinion           |
| <b>Status</b>                | Recruitment stopped        |
| <b>Health condition type</b> | -                          |
| <b>Study type</b>            | Observational non invasive |

## Summary

### ID

NL-OMON25944

### Source

NTR

### Brief title

FOCOM NIRS studie

### Health condition

aging - veroudering  
working memory - werkgeheugen  
response inhibition - response inhibitie

## Sponsors and support

**Primary sponsor:** Wageningen University, division of Human Nutrition

**Source(s) of monetary or material Support:** European Fund for Regional Development (EFRO), the province of Gelderland and the national government

## Intervention

## Outcome measures

### Primary outcome

Oxygenated (O2Hb) and deoxygenated (HHb) hemoglobin concentration changes (μmol/L), measured during baseline and the performance of the cognitive paradigm

### **Secondary outcome**

- Total hemoglobin changes (O2Hb + HHb) (μmol/L), measured during baseline and the performance of the cognitive paradigm
- EEG frequency bands measured during baseline and the performance of the cognitive paradigm
- Blood pressure (mmHg), measured during baseline and the performance of the cognitive paradigm
- Heart rate (bpm), measured during baseline and the performance of the cognitive paradigm
- Exhaled CO2 (%), measured during baseline and the performance of the cognitive paradigm
- Performance on the cognitive tasks
- Hospital Anxiety and Depression Scale (HADS)
- Short Questionnaire to Assess Health enhancing physical activity (SQUASH)
- Barratt Impulsiveness Scale (BIS-11)
- Cognitive Failure Questionnaire (CFQ) (only older adults group)
- Performance on the additional neuropsychological test battery

## **Study description**

### **Study objective**

This study tests the hypothesis that age has an effect on prefrontal brain activity, measured by fNIRS and EEG, during a cognitive paradigm assessing proactive response inhibition and working memory.

The results of the fNIRS-EEG study will be compared with the results of a fMRI study with the same cognitive paradigm

### **Study design**

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## Intervention

We will measure cerebral blood flow (with fNIRS) at the prefrontal cortex, and electrical activity (with EEG) at the scalp in young and elderly healthy subjects, during the performance of a working memory task and a response inhibition task. The study has a cross-sectional design and no intervention is applied.

## Contacts

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## Eligibility criteria

### Inclusion criteria

- Males and females aged 18-35 years (young adults group)
- Males and females aged 60-75 years (older adults group)
- Right-handed
- Dutch speaking
- Good health (see exclusion criteria)
- Non-smoking (max. 1 cigarette per day)
- Normal or corrected-to-normal vision

- Signed informed consent available

## Exclusion criteria

- Mini-Mental State Examination (MMSE) score  $\geq 26$  (older subjects group)
- Estimated IQ < 85 (based on Nederlandse Leestest voor Volwassenen [NLV]-score)
- Colour blindness
- Current or past psychiatric disorder, such as psychosis or major depression.
- Current or past neurological disorder, such as severe cerebral vascular disease (e.g. cortical stroke, subarachnoid hemorrhage), Parkinson's disease, epilepsy, traumatic brain injury, central nervous system infection, brain tumor, and alcoholic encephalopathy
- Current or past severe systemic disease such as coronary artery disease, myocardial infarction <6 months, heart failure (unstable), chronic obstructive pulmonary disease (unstable)
- Type 1 or type 2 diabetes mellitus
- Previous head surgery
- Excessive alcohol use (on average >3 consumptions per day)
- Recurrent migraine
- General medical conditions, such as repetitive strain injury (RSI), which may confound the results of the study, as judged by the investigator
- Use of psychopharmacological drugs (anxiolytics, antidepressants, antipsychotic drug, long-acting benzodiazepines etc.)
- Use of cardiovascular drugs (including antihypertensives)
- Current participation in another study or previous participation in the fMRI study of the Donders Institute of Brain, Cognition and Behaviour, Nijmegen.

## Study design

## Design

|                     |                            |
|---------------------|----------------------------|
| Study type:         | Observational non invasive |
| Intervention model: | Parallel                   |
| Allocation:         | Non controlled trial       |
| Masking:            | Open (masking not used)    |
| Control:            | N/A , unknown              |

## Recruitment

|                           |                     |
|---------------------------|---------------------|
| NL                        |                     |
| Recruitment status:       | Recruitment stopped |
| Start date (anticipated): | 01-07-2014          |
| Enrollment:               | 40                  |
| Type:                     | Actual              |

## Ethics review

|                   |                  |
|-------------------|------------------|
| Positive opinion  |                  |
| Date:             | 10-06-2014       |
| Application type: | First submission |

## 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     |
|----------|--------|
| NTR-new  | NL4137 |

**Register**

NTR-old

Other

**ID**

NTR4641

CMO Regio Arnhem-Nijmegen : 2014/029

## Study results