The direct effect of cerebral blood flow perturbations on cerebral perfusion and cognitive performance in healthy elderly people

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON42934

Source
ToetsingOnline

Brief title
EXERT

Condition

- Dementia and amnestic conditions

Synonym
mild cognitive impairment, mild memory problems

Research involving
Human

Sponsors and support

Primary sponsor: Geriatrie

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cerebral blood flow, cognitive performance, elderly, prefrontal oxygenation

Outcome measures

Primary outcome

Changes in functional prefrontal activation as determined by oxygenated

hemoglobin changes (µmol/L) induced by cerebral blood flow perturbations.

Secondary outcome

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Study description

Background summary

Human and animal studies show the positive effects of regular physical exercise on cognitive functioning. Epidemiological studies have shown that leisure-time physical activity at midlife is associated with a decreased risk of Alzheimer disease (AD) later in life. The underlying mechanisms by which exercise could modify cognitive performance in humans remains largely unclear. This project aims to unravel the potential role of cerebral blood flow regulation as a key factor, or mediator, for the beneficial effects of exercise on brain function.

Study objective

The primary objectives are to study how exercise (i.e. actively performing exercise) affects frontal cortical activation (neurovascular coupling) and the effects on immediate cognitive performance of short periods of reduced and enhanced cerebral blood flow in healthy elderly participants.

Study design

This is an intervention study with a cross-over design.

Intervention

Healthy older adults will visit the hemodynamics laboratory three times. During

one visit participants will have to perform sit-to-stand alternations for four times five minutes in total, with intervals of one minute. During another visit participants will exercise on a pedal exercise at 65% of their theoretical maximum heart rate for approximately 40 minutes. To minimize effects of fatigue, participants will be able to rest 10 minutes halfway the task.

Study burden and risks

Given the established safety of the noninvasive techniques there are no foreseeable risks associated with participation in this study. A considerable burden will be placed on the participating healthy elderly because the three lab visits are time-consuming.

Contacts

Public
Selecteer

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Scientific
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Males and females aged >=60
Living independently at home
Physical ability sufficient to allow performance of exercise
Normal or corrected-to-normal vision
Stable medical condition for more than 6 months
Stable medications for more than 2 months

Exclusion criteria

Experience of subjective memory problems
History of serious neurological disorder
History of any major psychiatric disorder
Significant history of alcoholism or drug abuse within the last 10 years
History of myocardial infarction within previous year
Unstable cardiac, renal, lung, liver, or other chronic disease
Uncontrolled hypertension or hypotension
Congestive heart failure (NYHA class II, III or IV)
Diabetes
Use of psychopharmacological drugs

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-03-2016
Enrollment:	15

Type:	Actual

Ethics review

Approved WMO Date:	14-03-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL56843.091.16