

# NEUROcognitive fitness: Studying changes in Hippocampal Adult neurogenesis and cognition induced by Physical Exercise

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Primary objective:- To investigate if exercise can modulate neurogenesis and angiogenesis in vivo, and whether this is associated with changes in hippocampal function, such as pattern separation  
Secondary objectives:- To assess whether exercise-...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON43536

### Source

ToetsingOnline

### Brief title

NEURO-SHAPE

### Condition

- Other condition

### Synonym

Neurogenesis

### Health condition

hersenplasticiteit

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Academisch Medisch Centrum

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

## Intervention

**Keyword:** Angiogenesis, Cognition, Exercise, Neurogenesis

## Outcome measures

### Primary outcome

To compare the effects of 12 weeks 3x weekly aerobic exercise in healthy volunteers on:

- Neurogenesis
- Angiogenesis
- Hippocampal function (e.g. pattern separation)

### Secondary outcome

To compare the effect 12 weeks 3x weekly aerobic exercise in healthy volunteers on:

- VO2max
- Hippocampal volume
- Neuronal and endothelial growth factors in serum
- Neuropsychological functioning: memory and executive function
- Questionnaires assessing lifestyle and dietary patterns

## Study description

### Background summary

Physical exercise is not only beneficial for general health, but has also been shown to improve brain function (cognition) and influence brain structure (increase brain volume, especially in the hippocampus). However, the underlying neural mechanisms that cause this increase in volume are relatively unknown. Animal studies have shown that physical exercise can increase the formation of new neurons, a process called neurogenesis, and the survival of these neurons. In addition, these new neurons have been demonstrated to be involved in cognition, especially in hippocampal-dependent pattern separation. We hypothesize that exercise could also increase neurogenesis in the human hippocampus. The recently developed and validated non-invasive magnetic resonance spectroscopy (MRS) now allows to reliably detect neurogenesis for the first time in the live human brain.

Exercise has also been demonstrated to influence the formation of new blood vessels (angiogenesis) in the hippocampus in rodents, a process which is closely linked to neurogenesis. Angiogenesis can be measured in the human brain by contrast-enhanced MRI, exploiting the leakiness of new vessels. In this study, we aim to study the effect of exercise on neurogenesis and angiogenesis and elucidate the link to brain function in the hippocampus.

## **Study objective**

Primary objective:

- To investigate if exercise can modulate neurogenesis and angiogenesis in vivo, and whether this is associated with changes in hippocampal function, such as pattern separation

Secondary objectives:

- To assess whether exercise-induced changes in VO<sub>2</sub>max correlate with changes in neurogenesis and angiogenesis
- To assess whether BDNF levels in serum correlate with changes of VO<sub>2</sub>max, neurogenesis and angiogenesis
- To assess exercise-induced changes in hippocampal volume
- To assess exercise-induced changes in neuropsychological functioning
- To assess exercise-induced changes in lifestyle and dietary patterns

## **Study design**

Randomized controlled exercise intervention study.

## **Intervention**

Subjects will be randomized to either the exercise or control group. The subjects in the exercise group will engage in 3x weekly sessions of aerobic exercise, whereas the control group will engage in 3x weekly stretching exercises.

## Study burden and risks

Risk assessment:

- The placing of the IV cannula in our study for contrast administration can be an unpleasant experience for the subjects. There is a low risk of phlebitis at the IV injection sites, this is unpleasant, but not harmful, of temporary nature and self-limiting. Adverse events to the contrast agent are rare.
- MRI is a non-invasive imaging modality. All volunteers will receive extensive information about the MRI procedures beforehand. Volunteers suffering from claustrophobia will be excluded.
- The CPET is routinely used in clinical practice to assess physical stamina. Adverse effects as a consequence of this test are extremely rare
- The aerobic exercise intervention as well as the stretching and toning intervention is considered to be safe for subjects this age. In case of adverse effects caused by exercise, subjects will be examined by the supervising doctor and advised to see the physiotherapist or general practitioner. If the subject is willing to continue participation in the study, the medical specialist will decide if continuing in the study is still safe for the subject.

Benefit

Subjects will engage in regular exercise. Exercise has several physical and mental health benefits and is associated with a better quality of life. Furthermore, the subjects in this study can contribute to the knowledge on how exercise can be utilized to increase neurogenesis, better vascularization and improved cognition \* and be beneficial as (adjunctive) treatment for a number of neuropsychiatric and neurodegenerative disorders.

## Contacts

### Public

Academisch Medisch Centrum

Spui 21  
Amsterdam 1012 WX  
NL

### Scientific

Academisch Medisch Centrum

Spui 21  
Amsterdam 1012 WX  
NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Age 18-30 years
- BMI \* 30 kg/m<sup>2</sup>
- VO<sub>2</sub>max \* 55 ml/kg/min (males), \* 45 ml/kg/min (females)
- Stable exercise history 3 months prior to study inclusion

### Exclusion criteria

- General contraindications for MRI (such as claustrophobia)
- History of chronic renal insufficiency
- History of allergic reaction to Gadolinium-containing compounds
- History of any psychiatric disorder
- Intensive sports (>3/week)
- Excessive smoking (>1 pack/day), alcohol (>21 units/week), and other regular drug use

## Study design

### Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Basic science

## Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2016
Enrollment:	57
Type:	Actual

## Ethics review

Approved WMO	
Date:	18-02-2016
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	11-07-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	07-09-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC

## 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: 29541  
Source: NTR

Title:

## In other registers

Register	ID
CCMO	NL55943.018.15
OMON	NL-OMON29541