Het effect van beweging op de bloeddoorstroming in de hersenen bij patiënten met vasculaire cognitieve stoornissen

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22385

Source
NTR

Brief title
ExCersion-VCI

Health condition

Vascular cognitive impairment,
Aerobic exercise,
Cerebral blood flow,
Arterial spin labeling

Sponsors and support

Primary sponsor: VU University Medical Center
Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Cardiovasculair Onderzoek Nederland (CVON)

Intervention

Outcome measures

Primary outcome

• Change in cerebral blood flow (CBF), measured with Arterial Spin-Labeling-Magnetic Resonance Imaging (ASL-MRI).

Secondary outcome

• Change in cognitive functions on neuropsychological testing;
• Change in brain structure;
• Change in physical fitness;
• Change in blood biomarkers;
• Change in (i)ADL, neuropsychiatric measures and quality of life;

• Change in cerebral autoregulation;

• Change in cerebral vasomotor reactivity;

Study description

Background summary

The ExCersion-VCI is a multi-center, single-blind randomized controlled trial among 80 non-demented patients with VCI. Patients with VCI are recruited from two medical centers (VU University medical center and University Medical Center Utrecht). Participants are randomized into an aerobic exercise program (n = 40) or into a control condition (n = 40). The aerobic exercise program aims to improve cardiorespiratory fitness. The primary outcome measure is change in CBF, measured with Arterial Spin-Labeling-Magnetic Resonance Imaging (ASL-MRI). Secondary outcome measures include change in cognitive and physical functioning, change in brain function and structure, change in blood biomarkers and change in iADL and quality of life.

Study objective

We aim to assess whether aerobic exercise leads to increased cerebral perfusion in patients with vascular cognitive impairment.

Study design

Screening

Baseline

Follow-up (after intervention period)

Intervention

Participants are randomly assigned to either the aerobic exercise program or to the usual care control group. The aerobic exercise program aims to improve the cardiorespiratory fitness of the participants. Participants are provided with a bicycle ergometer at home, on which they are asked to perform the exercise sessions.

The total exercise program takes 14 weeks. Sessions take place three times a week for approximately 45 minutes. Each session consists of a warming-up (10 minutes), a core activity (25 min) and a cooling-down (10 min).

Contacts

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Eligibility criteria

Inclusion criteria

• Age: ≥50 years.

• Cognitive complaints

• Independency in daily life.

• Clinical Dementia Rating (CDR) score ≤ 0,5 and Mini Mental State Examination (MMSE) ≥ 22.

• Presence of a primary caregiver.

Furthermore, at least one of the following criteria should be present:

• On brain MR, moderate to severe white matter lesions (Fazekas > 1) and/or (lacunar) infarct(s) and/or intracerebral (micro-)haemorrhage(s).

• On brain MR, mild white matter lesions (Fazekas = 1) and at least two of the following vascular risk factors: hypertension, hypercholesterolemia, diabetes mellitus, obesity, smoking or clinically manifest vascular disease (last event > 6 months ago). Clinically manifest vascular disease comprises peripheral arterial disease, myocardial infarction, percutaneous coronary intervention (PCI)/coronary artery bypass graft (CABG), and/or stroke.

Exclusion criteria

• Diagnosis of dementia.
• Contra-indication for MRI or unable to undergo MRI protocol due to a physical condition.
• Participation in aerobic exercise program (moderate-to-hard intensity) ≥ twice weekly on a regular basis.
• Major neurological (e.g. Parkinson’s disease, multiple sclerosis), cardiac (e.g. heart-failure, severe aorta stenosis, cardiac rhythm disturbances) or other medical disease that affects cognition and mobility and constitutes a contra-indication to perform aerobic exercise training.
• Clinically significant peripheral neuropathy or severe musculoskeletal or joint disease that impairs mobility.
• Other neurological diagnosis, such as severe traumatic brain injury, or major psychiatric disorder, such as psychosis, schizophrenia, severe personality disorder or depression with vital signs, alcohol abuse or other substances, that could affect cognitive performance during neuropsychological assessment.
• Participation in on-going trials for therapeutic interventions including randomized controlled trials and clinical trials investigating medicinal products.

• Insufficient proficiency of the Dutch language.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-10-2015
Enrollment:	80
Type:	Anticipated

Ethics review

Positive opinion

Date:	27-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47838
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5547

Register	ID
NTR-old	NTR5668
CCMO	NL51973.029.15
OMON	NL-OMON47838

Study results