The effect of aerobic exercise on cerebral perfusion in patients with vascular cognitive impairment

Published: 04-05-2015
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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Dementia and amnestic conditions
Study type	Interventional

Summary

ID

NL-OMON47838

Source
ToetsingOnline

Brief title
ExCersion-VCI

Condition

- Dementia and amnestic conditions

Synonym
Vascular Cognitive Impairment / Cognitive complaints by problems in the supply of blood to the brain

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: CardioVasculair Onderzoek Nederland (CVON)

Intervention

Keyword: Arterial Spin Labeling, Cerebral perfusion, Exercise, Vasculair cognitive impairment

Outcome measures

Primary outcome

Change in cerebral perfusion, measured with arterial spin labeling (ASL) - MRI

Secondary outcome

Change in cognitive functions on neuropsychological testing;

Change in cardiac function and structure (measured with parameters on cardiac

MRI);

Change in brain structure (measured with parameters on brain MRI);

Change in physical fitness;

Change in blood biomarkers;

Change in neuropsychiatric measures and quality of life;

Change in cerebral autoregulation and cerebral vasomotor reactivity;

Study description

Background summary

Over the last 40 years, the relationship between physical activity and cognitive functioning has been studied in cross-sectional, prospective and longitudinal studies. These studies show a positive relationship between physical activity and cognitive functioning. Randomized controlled trials (RCTs) show that aerobic exercise improves cognitive functioning, in particular executive functioning, in healthy elderly. Research in patients with cognitive disorders and dementia show mixed results, possibly by methodological problems. Vascular cognitive impairment (VCI) is one of the most important causes of cognitive impairment and dementia. Despite the increasing prevalence of cerebrovascular disease, few intervention studies focus on non-pharmacological treatment for this specific group. One promising approach to delay or prevent

the progression of VCI might be aerobic exercise. The biological mechanism underlying the positive effect of physical activity on cognitive functioning is poorly understood. Understanding the mechanism is essential to support the use of physical activity as preventive therapy. Available data have lead to the hypothesis that the possible beneficial effect of aerobic exercise on cognition is explained by an improved CBF, which might be mediated by an improved cardiac output.

Study objective

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

Study design

Multi-center single-blind randomized controlled trial.
All participants will undergo the same standardized set of clinical, neuropsychiatric, physical fitness and imaging tests to assess cognitive functioning, daily functioning, presence of neuropsychiatric symptoms and the structural and functional brain and cardiac status. After baseline measurement, participants in the intervention-group will receive an aerobic exercise program, while the control group doesn't. After 14 weeks the same standardized set of tests will be repeated.
Participants will be invited to participate in a sub study to assess the effect of aerobic exercise on cerebral auto regulation and cerebral vasomotor reactivity.

Intervention

Participants are randomized into an aerobic exercise program or into a control condition. The aerobic exercise program aims to improve cardiorespiratory fitness. The program takes 14 weeks in total, with a frequency of 3 times a week (42 sessions in total). Participants are provided with a bicycle ergometer at home. Each session consists of an interval training, based on the peak heart rate. Of the 42 exercise sessions, 13 sessions are supervised by an student physical therapy. Supervised sessions are frequent in the beginning of the intervention program and become less frequent during the course of the program. Participants in the control condition receive two information meetings during which information about VCI is provided, in addition to usual care.

Study burden and risks

All research data are collected through standard medical procedures and no experimental intervention is conducted. The additional risk of this study is considered negligible. The burden of participation consists of time investment at both baseline and follow-up measurements (approximately 6 hours per

measurement). Participants in the intervention-group will also invest time in their aerobic exercise program (approximately 42 hours). However, this study will contribute to knowledge of the effect of physical activity on cerebral perfusion.

Contacts

Public
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HV
NL
Scientific
Vrije Universiteit Medisch Centrum

De Boelelaan 1118
Amsterdam 1081 HV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with vasculair cognitive impairment, age: 50-80yr, cognitive complaints, independency in daily life, clinical dementia rating <= 0 / 0,5; MMSE >22, presence of a primary caregiver

Exclusion criteria

Diagnosis of dementia; contra-indication for MRI; major neurological / psychiatric / cardiac or other medical disease that affects cognition and mobility

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	05-10-2015
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	04-05-2015
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	27-07-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	06-11-2015

Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-01-2016
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	13-02-2018
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	11-06-2019
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: 22385
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL51973.029.15
OMON	NL-OMON22385