The effects of an extensive exercise program on the progression of mild cognitive impairment (MCI) and cerebral perfusion regulation

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This project aims to determine the effects of an extensive exercise program in MCI patients with respect to the progression of the disease

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

Summary

ID

NL-OMON42347

Source
ToetsingOnline

Brief title
NeuroExercise

Condition

- Dementia and amnestic conditions

Synonym
Mild cognitive impairment, starting memory problems

Research involving
Human

Sponsors and support

Primary sponsor: Geriatrie
Source(s) of monetary or material Support: Joint progamme Neurodegenerative

research (JPND)

Intervention

Keyword: Cognition, Exercise, Mild cognitive impairment, Physical fitness

Outcome measures

Primary outcome

The primary outcome is cognitive performance, determined by a

neuropsychological test battery.

Secondary outcome

Secondary outcomes are physical fitness, cerebral autoregulation,

cerebrovascular reactivity, prefrontal oxygenation, arterial stiffness,

endothelial function, quality of life, epigenetics and cerebral structure

Study description

Background summary

A lack of physical exercise plays a major role in the pathophysiology of vascular, metabolic, and metastatic diseases. Regular physical exercise has been successfully proven to counteract this deconditioning. Human and animal studies have demonstrated that regular physical activity targets brain function by increasing cognitive reserve. There is also evidence of structural changes caused by exercise in preventing or delaying the genesis of neurodegeneration. A considerable number of studies have targeted the effects of physical activity on functional and structural brain changes in patients at greater risk for Alzheimer*s disease (AD). Epidemiological studies have shown that leisure-time physical activity at midlife is associated with a decreased risk of dementia and AD later in life. Although initial studies indicate enhanced behavioural performance in dementia patients after three months of exercise, little is known about the effect of an extensive, controlled and regular exercise regimen on the progressive neuropathology of patients with MCI.
It is hypothesized that mild cognitive impairment (MCI)-related specific decreases in cognitive and psychomotor functioning will show less progression or even be improved after a one-year aerobic exercise intervention as compared to a group of patients undergoing non-aerobic exercise (gymnastic exercises) as

well as to a control group provided with no intervention.

Study objective

This project aims to determine the effects of an extensive exercise program in MCI patients with respect to the progression of the disease

Study design

Single blind randomised intervention study with pragmatic approach. The two training groups are randomized, the contropgroup is not randomised. The controlgroup consists of participants eligible to participate, but for whom it is practical not possible to participate, for example due to living too far away.

Intervention

Patients are classified in 3 groups. One group receives a standardized one-year extensive aerobic exercise intervention (3 units à 45min / week, according to WHO recommendations). The second group receives non-aerobic exercise (3 units à 45min / week) and the third group is provided with no intervention.

Study burden and risks

Participants of this study will visit the Radboudumc 7 times in one year, taking approximately
18 hours in total. Only non-invasive measurements will be performed and all procedures have been used on healthy MCI patients before and were well tolerated.
The training sessions of the aerobic and non-aerobic will cost about 150*45 minutes=112 hours. The exercise intervention will be safe for elderly with MCI, as is piloted before. Only muscle soreness and tiredness may be caused by the training. The aerobic and non-areobic intervention are expected to be beneficial for cognition and physical functioning. Also the social part may be important of the study. By training in groups, people are socially active and experience the trainings as fun together.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Diagnosis of Mild cognitive impairment (MCI) (Peterson criteria or practical identification)
Physical ability sufficient to allow performance of endurance exercise training

Exclusion criteria

Diagnosis of dementia/Alzheimer's disease
Engagement in moderate-intensity aerobic exercise training for more than 30 minutes, 3 times per week, during past 2 years
History of brain damage
History of myocardial infarction
Unstable chronical disease
Uncontrolled hypertension

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):	07-03-2016
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	05-01-2016
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	NL54544.091.15