Train the sedentary brain: move smart to reduce the risk of dementia;Sub study: Alternating aerobic and strength exercise in APOEe4 carriers and non-carriers in early stage dementia: effects and dose-response relation

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

Summary

ID

NL-OMON41982

Source
ToetsingOnline

Brief title
Aerobic and strength exercise in dementia

Condition

- Dementia and amnestic conditions

Synonym
Dementia; Alzheimer Disease

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW Deltaplan Dementie Memorabel

Intervention

Keyword: Cognition, Dementia, Exercise, Physical function

Outcome measures

Primary outcome

Main outcome measure is cognitive function, measured with neuropsychological tests.

Secondary outcome

Secondary outcome measures are physical functioning measured with performance-based field tests, and ADLS, mood and quality of life, measured by questionnaire.

Study description

Background summary

There is no cure for dementia. Physical activity could be an alternative to medications in an effort to slow the dementia-related cognitive decline. In healthy older subjects physical activity leads to improved cognition. In people with dementia the results are mixed, although a recent study revealed beneficial cognitive effects of alternating aerobic and strength exercise in people with moderate to moderate-severe dementia. Whether these effects hold in an earlier stage of the disease is unknown. In addition, a dose-response is not established yet and it is unknown whether effects are moderated by APOEe4 status, the most important biological risk factor of dementia. Furthermore, the underlying mechanisms through which exercise influences cognition are understudied in patients with dementia.

Study objective

Main objectives are to investigate the cognitive effects of alternating endurance-strength training in APOEe4 carriers and non-carriers in early stage dementia and to identify a dose-response relationship of the cognitive effects of exercise.
Secondary objective is to investigate the physical effects of this training regimen.
We expect that alternating endurance and strength training is feasible and leads dose-dependently to improved cognition and physical fitness. We expect stronger effects in APOEe4 carriers than in non-carriers. In addition, we expect IGF1 to mediate the association between exercise and cognition.

Study design

The design is a single blinded RCT with a cross-over element (low intensity versus higher intensity).

Intervention

The experimental group receives alternating aerobic-strength exercise, 3 sessions per week for 30 minutes, 12 weeks with low intensity and 12 weeks with high intensity. The control group receives stretching exercises and recreational activities with matched attention with the same duration and frequency.

Study burden and risks

The burden consists of participation in the intervention (36 hours), measurements (approximately 5.5 hours) and venapunction (approximately 40 minutes) over a period of 24 weeks. The exercises and tests are safe and feasible for older people with dementia. All activities in this study are within the range of normal activities of daily life. Participants are guided individually and they stay in their own familiar environment. However, minor muscle pain or tiredness may occur occasionally. For the experimental group anticipated benefits are improvements in cognition, physical functioning, ADLs, mood and quality of life. For the control group we anticipate benefits in muscle flexibility, specific ADLs, mood and quality of life. Both groups receive a lot of attention, which is generally experienced as pleasant.

Contacts

Public
Universitair Medisch Centrum Groningen

A. Deusinglaan 1

Groningen 9713AV
NL
Scientific
Universitair Medisch Centrum Groningen

A. Deusinglaan 1
Groningen 9713AV
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Age >= 65 years
Diagnosis of dementia
Visiting daycare at least three times a week
Able to perform the Timed Up & Go Test with or without assistive device
Mini Mental State Examination (Folstein and Folstein 1975) score > 10.

Exclusion criteria

Wheelchair bound
Cardiovascular problems that limit physical activity
Brain trauma
Epilepsy
Progressive or terminal disease
Depression
History of alcoholism
Severe visual problems
Severe auditory problems
Problems with the Dutch language

Mental incompetence

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2015
Enrollment:	118
Type:	Actual

Ethics review

Approved WMO Date:	24-02-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	19-10-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	24-03-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO Date:	01-11-2017
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 26925
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL51498.042.14
OMON	NL-OMON26925