Physical activity and cognition in early-onset dementia.

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This study exists of two parts:Cross-sectional study: what are the precise characteristics of physical functioning in EOD patients in comparison to a control group? Not all EOD patients show apathy and physical inactivity. It will be examined...

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

Summary

ID

NL-OMON37056

Source
ToetsingOnline

Brief title
Physical activity in early-onset dementia.

Condition

- Dementia and amnestic conditions

Synonym
early-onset dementia, presenile dementia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: Roomsch Catholijk Oude Armen Kantoor (RCOAK)

Intervention

Keyword: cognition, early-onset dementia, physical activity, physical functioning, rest-activity rhythm

Outcome measures

Primary outcome

Primary study parameters in the cross-sectional study will be measures concerning physical functioning (question 1a) and measures concerning global cognitive functioning, mental speed, and executive functioning (question 1b).

Primary study parameters in the intervention study will be measures concering global cognitive functioning, mental speed, instrumental activities of daily living, and quality of live.

Secondary outcome

Secundary measures concern mood and rest-activity rhythm.

Study description

Background summary

Development of early-onset dementia (EOD) is very radical and disabling for both patient and family, due to the still prominent role of the patient in society. Except for knowledge on cognitive disorders not much is known about other disabling disorders in EOD. Several characteristics of EOD, like apathy and loss of initiative, could lead to motor inactivity, which can lead to motor disability. Strong evidence is found on a strong association between physical aerobe activity and cognition in people of both middle age as in the elderly.

Study objective

This study exists of two parts:
Cross-sectional study: what are the precise characteristics of physical functioning in EOD patients in comparison to a control group? Not all EOD patients show apathy and physical inactivity. It will be examined whether cognitive differerences are present between EOD patients who are physically

active and EOD patients who are not.
Intervention study: Is an aerobe activity program able to slow down the progressive nature (concerning cognition (especially executive functioning), mood, and rest-activity rhythm in EOD patients who participate in such a program in comparison to EOD patients who participate in a flexibility program (which is non-aeroob)? Is an aeroob activity program able to slow down the progressive nature to a higher extent when the program is directly guided in contrast to when the program is indirectly guided?

Study design

Centre randomised intervention study.

Intervention

Participants with EOD who participate in the intervention part of this study will be randomised into a 3 month enduring program: Directly Guided Aerobe Activity Program (aerobe activity, such as running, 3 times al week, 60 minutes); Directly Guided Flexibility Program (flexibility training and relaxation exercises); Indirectly Guided Aerobe Activity Program (*therapy*, stimulation of aerobe activity at home).

Study burden and risks

The risks are minimal, during the intervention there will be guarded against falling. Patients could be burdened by the neuropsychological and motor assessment, which can be tiring.

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

Main study:
- Diagnosis of early-onset dementia (onset of complaints < 66 years) (among others Alzheimer's disease, Vascular dementia, Frontotemporal dementia).
- Relatively early stage of dementia (MMSE * 16)
- Primary caregiver available;Extension:
- Diagnosis of (pre)senile dementia, or presence of similar symptoms due to a different condition.
- Participant has to be able to walk, or when the participant is bound to a wheelchair he has to be physically active.
- Gradual progression of cognitive disorders

Exclusion criteria

Main study:
- Bound to a wheelchair
- Neurodegenerative diseases at which motor symptoms are the primary problems, such as M. Parkinson and M. Huntington.
- Cardiovascular problems, such as severe cardiac problems or severe hypertension.
- Abuse of alcohol or other substances
- Trauma capitis in the medical history, at which a loss of consiousness was present of more than 15 minutes
- Extended history of psychiatry (major depression , bipolar disroder, psychosis)
- Severe visual problems
- Severe auditive problems
- Insufficient mastery of the Dutch language;Extension: same exclusion criteria

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-02-2010
Enrollment:	262
Type:	Actual

Ethics review

Approved WMO Date:	24-11-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-04-2011
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

No registrations found.

In other registers

Register	ID
CCMO	NL27426.029.09