

# Physical activity in early-onset dementia.

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<b>Ethische beoordeling</b>	Positief advies
<b>Status</b>	Werving nog niet gestart
<b>Type aandoening</b>	-
<b>Onderzoekstype</b>	Interventie onderzoek

## Samenvatting

### ID

NL-OMON22143

### Bron

Nationaal Trial Register

### Verkorte titel

EXERCISE-ON: EXERCISE and Cognition In Sedentary adults with Early-ONset dementia.

### Aandoening

ENG:

- Early-onset dementia
- Presenile dementia
- Presenile Alzheimer's disease
- Frontotemporal dementia
- Vascular dementia
- Lewy-body dementia
- Physical activity
- Exercise

NL:

- Preseniele dementie
- Jong-dementerenden
- Preseniele Ziekte van Alzheimer
- Frontotemporale dementie
- Vasculaire dementie
- Lewy-body dementie
- Fysieke activiteit
- Bewegen

- Sport

## Ondersteuning

**Primaire sponsor:** VU University Amsterdam

**Overige ondersteuning:** Rooms Catholijk Oude Armen Kantoor (RCOAK), Amsterdam, the Netherlands.

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

1. Global cognitive functioning: Alzheimer Disease Assessment Scale (ADAS)-COG; <br>
2. Mental speed: Trailmaking test A (TMT A); <br>
3. Executive functioning (flexibility): Trailmaking test B (TMT B); <br>
4. Instrumental Activities of Daily Functioning: Disability Assessment for Dementia (DAD); <br>
5. Quality of Life: Dementia-Quality of Life (D-QOL).

## Toelichting onderzoek

### Achtergrond van het onderzoek

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. Evidence is found on a strong association between physical aerobic activity and cognition in both people of middle age as in the elderly.

In our study three different exercise programs are offered to persons with early-onset dementia. We will investigate which program is able to slow down the progressive course of the symptoms of dementia.

### Doel van het onderzoek

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. Evidence is found on a strong association between physical

aerobe activity and cognition in both people of middle age as in the elderly.

Researchquestion:

Three different exercise programs are offered to persons with early-onset dementia: Aerobe Activity Program; Non-aerobe Activity Program; Aerobe activity program at home. Which program is able to slow down the progressive course of the symptoms of dementia (regarding: cognition, instrumental activities of daily living, and quality of life)?

Hypothesis:

Given the positive effects found in animal studies, it is expected that the Aerobe Activity Program will show most beneficial effects on the symptoms of dementia in early-onset dementia.

### **Onderzoeksopzet**

1. Baseline measurement, before intervention;
2. Measurement after the intervention, 3 months after baseline measurement;
3. Measurement 6 months after baseline measurement.

### **Onderzoeksproduct en/of interventie**

1. Aerobe activity program:
  - a. Length: 3 months;
  - b. Frequency: 3 times a week;
  - c. Activity: primarily cycling on a cycle ergometer;
  - d. Setting: rehabilitation centre.
2. Flexibility program:
  - a. Length: 3 months;
  - b. Frequency: 3 times a week;
  - c. Activity: flexibility exercises and relaxation exercises;

- d. Setting: rehabilitation centre.
- 3. Aerobe activity program at home:
  - a. Length: 3 months;
  - b. Frequency: 3 times a week;
  - c. Activity: primarily cycling;
  - d. Setting: at home.

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

### Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosis of early-onset dementia (onset of complaints < 66 years) (among others: Alzheimer's disease, Vascular dementia, Frontotemporal dementia);
2. Relatively early stage of dementia (MMSE > 15);

3. Primary caregiver available.

## **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

1. Bound to a wheelchair;
2. Neurodegenerative diseases that primarily result in motor impairments, such as Parkinson's disease and Huntington's disease;
3. Cardiovascular problems, such as severe cardiac problems or severe hypertension;
4. Abuse of alcohol or other substances;
5. Trauma capitis in the medical history, in which a loss of consciousness was present of more than 15 minutes;
6. Extended history of psychiatry (major depression, bipolar disorder, psychosis);
7. Severe visual problems;
8. Severe auditive problems;
9. Insufficient mastery of the Dutch language.

## **Onderzoeksopzet**

### **Opzet**

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blinding:	Enkelblind
Controle:	Placebo

### **Deelname**

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2009

Aantal proefpersonen:	180
Type:	Verwachte startdatum

## Ethische beoordeling

Positief advies	
Datum:	23-11-2009
Soort:	Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

Register	ID
NTR-new	NL2007
NTR-old	NTR2124
Ander register	METc VUmc : 2009/220
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Resultaten

### Samenvatting resultaten

N/A