

# Physical activity in early-onset dementia.

No registrations found.

<b>Ethical review</b>	Positive opinion
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON22143

### Source

NTR

### Brief title

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

### Health condition

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
- Frontotemporaal dementie
- Vasculaire dementie
- Lewy-body dementie
- Fysieke activiteit
- Bewegen
- Sport

## Sponsors and support

**Primary sponsor:** VU University Amsterdam

**Source(s) of monetary or material Support:** Roomsch Catholijk Oude Armen Kantoor (RCOAK), Amsterdam, the Netherlands.

## Intervention

## Outcome measures

### Primary outcome

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

### Secondary outcome

1. Physical functioning:
  - a. 6 minutes walk test;
  - b. Sit to stand test;
  - c. Physical Activity Scale for the Elderly (PASE).
2. Cognitive functioning:
  - a. Mini Mental State Examination (MMSE);
  - b. "Face recognition" and "Picture recognition" (subtest of the Rivermead Behavioural Memory Test (RBMT));
  - c. "Digit Span" (subtest of the Wechsler Memory Scale-Revised (WMS-R));
  - d. Fluency: category fluency and letter fluency;
  - e. Stroop colour word test;
  - f. "Symbol substitution" (subtest of the Wechsler Adult Intelligence Scale – III (WAIS-III));

- g. "Number location" (subtest of the Visual Object and Space Perception Battery (VOSP));
  - h. "Visual closure" (subtest of the Groninger Intelligence Test (GIT)).
3. Questionnaires:
- a. Dutch translation of the General Self-efficacy Scale;
  - b. Centre for Epidemiologic Studies Depression;
  - c. Rest-activity rhythm: actigraphy.

## 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. 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.

### Study objective

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.

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.

### **Study design**

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

### **Intervention**

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.

## Contacts

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## Eligibility criteria

### **Inclusion criteria**

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.

### **Exclusion criteria**

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.

## Study design

### Design

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

### Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2009
Enrollment:	180
Type:	Anticipated

## Ethics review

Positive opinion	
Date:	23-11-2009
Application type:	First submission

## 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
NTR-new	NL2007
NTR-old	NTR2124
Other	METc VUmc : 2009/220
ISRCTN	ISRCTN wordt niet meer aangevraagd.

## Study results

### Summary results

N/A