MoveIT, cognition and aerobic exercise after transient ischemic attack or minor stroke.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Interventional

Summary

ID

NL-OMON39313

Source
ToetsingOnline

Brief title
MoveIT

Condition

- Central nervous system vascular disorders
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
stroke, TIA

Research involving
Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis
Source(s) of monetary or material Support: Innovatiefonds Sint Lucas Andreas

Ziekenhuis en Stichting Roomsch Catholijk Oude Armen Kantoor

Intervention

Keyword: cognition, physical exercise, stroke, TIA

Outcome measures

Primary outcome

The primary outcome measure is global cognition, using the Montreal Cognitive Assessment (MOCA). This test is a frequently used tool to determine cognitive impaired after a TIA or minor stroke and is more sensitive for cognitive decline after stroke than the MMSE. Other important cognitive measures will be assessed in an extensive neuropsychological battery, including tests for executive function, attention, working memory, and verbal and non-verbal memory, emphasizing the executive functions. This assessment will be done by a blinded neuropsychologist.

Cardiorespiratory exercise capacity will be measured with the VO2max test, which measures the maximal amount of oxygen consumed by an individual's body. The VO2max will be determined in a maximal exercise test conducted on a cycle ergometer. This test will be performed in the pulmonary outpatient clinic and will be evaluated by the pulmonologist and cardiologist.

Secondary outcome

- Physical activity: this variable will be measured by the Physical Activity Scale for the Elderly (PASE) questionnaire. This questionnaire has been validated for elderly patients, also in the Netherlands. The score ranges from 0 to 400. The questionnaire consists of 12 items, asking about the frequency (per week) and the amount of time the patient spends on a certain activity.

- Fatigue: Fatigue Severity Scale

- Depression and anxiety: Hospital Anxiety and Depression Scale

- Cognitive complaints measured by the Cognitive Failure Questionnaire, to investigate the relationship between complaints of the patients and the findings in the neuropsychological examination.

- Cardiovascular risk: this combined measure consists of the reached targets for blood pressure (<140/90 mm Hg) ánd LDL-cholesterol (<2.5 mmol/L) ánd the use of antithrombotics or oral coagulants in the case of atrial fibrillation.

- Cardiovascular events or mortality: in the 2 year follow up all cardiovascular events and mortality will be documented.

- Imaging: At baseline all patients will have a CT-scan and MRI-scan of the brain. The amount of white matter hyperintensities, the amount of lacunar infarctions and the severity of the atrophy of the hippocampus and precuneus will be scored.

- Apolipoprotein E *4: in the literature this genetic factor has been linked to Alzheimer*s disease. This factor may also influence the effect of physical exercise on cognition and this factor possibly increases the risk of dementia after stroke. To exclude this factor as a possible confounder we will screen all patients.

- IQCODE: this is a validated questionnaire to determine cognitive decline before the TIA or stroke. This questionnaire will be filled out by the partner or kin of the patients.

Study description

Background summary

Patients with transient ischemic attack (TIA) or minor stroke have a high risk of recurrent stroke, myocardial infarction and death from vascular causes. In addition, they also have a high risk of cognitive decline and development of dementia. In several prospective trials 10% percent of patients developed dementia. However, the percentage of patients with mild cognitive impairment is even higher en varies between 30% and 70% depending on the criteria used. Patients with mild cognitive impairment have a higher risk of developing dementia, but the cognitive impairment can also remain stable or improve. Until now no intervention has been developed that can prevent cognitive decline after a TIA or stroke.
The majority of the patients after a TIA or stroke are physical inactive. In patients with coronary artery disease a cardiac rehabilitation program, which includes an exercise program decreases mortality. Despite the fact that patients after a TIA or stroke share the same risk factors, an exercise program for stroke patients has not been implemented yet. Apart from the possible positive effect of the exercise program on mortality in these patients, there are also strong indications for a positive effect on cognition. In the healthy population physical activity and an exercise program have a positive effect on cognition. The effect of an exercise program on cognition has not been investigated in patients after TIA or minor stroke before.

Study objective

The primary goal of this trial is to demonstrate that a physical activity program, which consists of an exercise program and follow-up care, under supervision of a specialized physiotherapist can prevent the frequently observed decline in global cognitive functioning in patients after TIA or minor stroke. Secondly, we want to investigate if a physical activity program improves the exercise capacity of patients after a TIA or minor stroke, in the short and long term.

Study design

We propose to perform a single-blind, randomized controlled single centre trial with an inclusion period of 1 year and a follow-up period of 1 year, with a second assessment at 2 years. All patients, who have recently suffered a TIA or minor stroke and meet the inclusion and exclusion criteria, will be asked to participate in the study. 120 patients will be included. Patients will be randomly assigned to group A, the control group, who will receive the standard care and group B, who are offered a physical activity program. Patients in group B will participate in a physical activity program, which consists of an

aerobic exercise program of 12 weeks and follow-up care under supervision of a physiotherapist. Outcome measures for all groups will be assessed at baseline and after 12 and 24 months of follow-up. This assessment consists of a neuropsychological assessment, a maximal exercise test, filling out questionnaires about physical activity, fatigue, depression and cognitive functioning, a venipuncture to measure the cholesterol level and a blood pressure measurement.

Intervention

Patients in group A, the control group, will not participate in an intervention and will only receive standard care. Patients in group B will participate in a physical activity program, which consists of an aerobic exercise program of 12 weeks and follow-up care by a physiotherapist. The exercise program consists of aerobic exercise and strength training, 2 times per week during 12 weeks. In week 2 of the exercise program patients will also start with 30-minute exercises 3 times per week at home. After the exercise program the patient will be seen in a follow-up care program by the physiotherapist at 6, 9 and 12 months after inclusion to maintain an active lifestyle.

Study burden and risks

Outcome measures will be assessed on 3 occasions during the two year follow-up. These assessments will cost the patient 15 hours overall. The outcome measures assessed in patients are relevant to the disorder of the patient and the interventions. The venipuncture is necessary to measure cholesterol and we will send the results to the general physician to prevent an unnecessary venipuncture. The VO2max measurement in a maximal exercise test is necessary to demonstrate the effect of the physical activity program on the cardiorespiratory exercise capacity of the patient. A maximal exercise test has a certain risk, particularly in patients who are not used to perform physical activity. In patients with latent cardiac disease a maximal exercise test can provoke cardiac complaints. Before this test we will always fill out a cardiac checklist with the patient, which has been developed and tested in an earlier pilot study. If necessary, the patient will be seen by the cardiologist prior to performing the test. There is always a pulmonary laboratory worker present who is trained in recognizing ECG-abnormalities or other reasons for terminating the test prematurely. A pulmonologist is available in case of medical calamities. The maximal exercise test is also necessary to determine the intensity of the exercise program by using percentages of the maximal heart rate and load.

Contacts

Public
Sint Lucas Andreas Ziekenhuis

Jan Tooropstraat 164
Amsterdam 1061AE
NL
Scientific
Sint Lucas Andreas Ziekenhuis

Jan Tooropstraat 164
Amsterdam 1061AE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients older than 18 years with a transient ischemic attack (TIA) or minor stroke less than 1 month ago
National Institute of Health (NIH) stroke scale < 4
Discharge to home without rehabilitation
Able to walk independently (if necessary with walking aid) and make transfers independently

Exclusion criteria

Severe aphasia or language barrier
(Cardiac or pulmonary) Contraindications for physical activity
Disease with assumed inability to perform physical activity
Dementia

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):	25-05-2012
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	24-05-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	01-07-2013
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

ID: 21582
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL38008.029.11
OMON	NL-OMON21582

Study results

Date completed: 31-12-2016

Actual enrolment: 120

Summary results
Trial is onging in other countries