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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21582

Source
Nationaal Trial Register

Brief title
MoveIT

Health condition

stroke
TIA
physical exercise
beroerte
lichaamsbeweging

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis
Source(s) of monetary or material Support: Innovation fund Sint Lucas Andreas Ziekenhuis
Stichting Roomsch Catholijk Oude Armen Kantoor

Intervention

Outcome measures

Primary outcome

1. The primary outcome measure is global cognition, using the Montreal Cognitive Assessment (MOCA). 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;

2. Cardiorespiratory exercise capacity will be measured with the VO2max test, which measures the maximal amount of oxygen consumed by an individual's body.

Secondary outcome

1. Physical activity measured by the Physical Activity Scale for the Elderly (PASE) questionnaire;

2. Fatigue assessed by means of the Fatigue Severity Scale;

3. Depression and anxiety by means of the Hospital Anxiety and Depression Scale;

4. Cognitive complaints measured by the Cognitive Failure Questionnaire;

5. 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;

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

Study description

Background summary

This study is a single-blind, randomized controlled single centre trial with an inclusion period of 1.5 year and a follow-up period of 1 year, with a second assessment at 2 years. All patients, who have recently suffered from 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. After informed consent, patients will be randomly assigned to the control group, who will receive standard care, or the physical activity program. The physical activity program 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.

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.

Study design

Outcome measures for all groups will be assessed at baseline and after 12 and 24 months of follow-up.

Intervention

After informed consent, patients will be randomly assigned to the control group, who will receive standard care, or the physical activity program.

The physical activity program 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.

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Eligibility criteria

Inclusion criteria

1. Patients older than 18 years with a transient ischemic attack (TIA) or minor stroke less than 1 month ago;

2. National Institute of Health (NIH) stroke scale < 4;

3. Discharge to home without rehabilitation;

4. Able to walk independently (if necessary with walking aid) and make transfers independently.

Exclusion criteria

1. Severe aphasia or language barrier;

2. (Cardiac or pulmonary) contraindications for physical activity;

3. Disease with assumed inability to perform physical activity;

4. Dementia.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	25-05-2012
Enrollment:	120
Type:	Anticipated

Ethics review

Positive opinion
Date: 06-03-2013
Application type: First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39313
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL3721
NTR-old	NTR3884
CCMO	NL38008.029.11
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39313

Study results

Summary results
N/A