MotiveS and MoveIT: chronic, multidisciplinary post-stroke care and aerobic exercise after transient ischemic attack or minor stroke - a pilot study

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1. To investigate whether a single-blind, randomized controlled trial in patients with a TIA or minor stroke addressing secondary prevention, healthy life style and cognition is feasible and not too demanding for the patient.2. To investigate…

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

Summary

ID

NL-OMON34944

Source
ToetsingOnline

Brief title
MotiveS and MoveIT - a pilot study

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: ZonMw-subsidie (praktijkproject Vitale Vaten)

Intervention

Keyword: cognition, exercise, secondary prevention, stroke

Outcome measures

Primary outcome

- % of patients who drop out during the trial

- % of patients who drop out due to the outcome of the cardiopulmonary

checklist , the consultation of the cardiologist or pulmonologist, the maximal

exercise test or the physical activity program.

- Reasons for premature terminating of the maximal exercise test or physical

activity program

- Satisfaction of the patient with provided care: measured by Satisfaction with

Stroke Care questionnaire

Secondary outcome

- Cardiovascular risk: the percentage of patients in whom the combined endpoint

is reached: both targets for blood pressure (<130/80 mm Hg) ánd LDL-cholesterol

(<2.5 mmol/L) ánd the use of antithrombotics

- Cardiorespiratory exercise capacity (VO2max) measured in a maximal exercise

test

- % of patients with a blood pressure equal or lower than the target value

- % of patients with a LDL cholesterol level equal or lower than the target

value

- % of patient using antithrombotics

- % of patients using antihypertensive therapy

- % of patients using statins

- % of patients achieving 5% weight reduction

- % of patients who quit smoking

- % of patient with alcohol abuse who have stopped drinking alcohol

- Medication adherence measured by Morisky questionnaire

- Physical activity measured by the Physical Activity Scale for the Elderly

- Cognition measured by neuropsychological assessment of 90 minutes

- Quality of life: Stroke Specific Quality of Life

- Fatigue: Fatigue Severity Scale

- Depression and anxiety: Hospital Anxiety and Depression Scale

- Endurance capacity: constant-load endurance test

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. It is thought that this risk can be decreased up to 80% by treatment with antithrombotics, antihypertensiva and statins, and addressing life style factors such as cessation of smoking and alcohol consumption, loosing weight and improving physical activity. However, neurovascular care in the Netherlands is dominated by acute stroke care. Chronic care for ambulatory stroke survivors is highly variable, and generally less well organized. In a survey by the Dutch Heart association in 2006 only 62% of ambulatory stroke survivors with raised blood pressure used an antihypertensive agent, and only 52% of patients with hypercholesterolemia received statins. Improving adherence to guidelines and lifestyle changes by standardized chronic poststroke care might be a powerful way to increase efficiency of secondary stroke prevention, but this has not been investigated before. Moreover, a cardiac rehabilitation program, which was

developed to influence lifestyle factors and improve physical activity, decreases mortality in patients with coronary artery disease. This has not been implemented for stroke, while patients share the same risk factors. After stroke patients have a higher chance of cognitive deterioration and developing dementia. In the healthy population physical activity has a positive effect on cognition. The effect of a physical activity program on cognition in patients with a TIA or minor stroke has not been investigated before.

Study objective

1. To investigate whether a single-blind, randomized controlled trial in patients with a TIA or minor stroke addressing secondary prevention, healthy life style and cognition is feasible and not too demanding for the patient.
2. To investigate whether a multidisciplinary poststroke care program has a positive effect on achieving adequate secondary prevention and achieving and maintaining an active and healthy lifestyle in patients after TIA or minor stroke.
3. To investigate whether an exercise program under supervision of a physiotherapist and multidisciplinary poststroke care program , will improve physical activity, promote adequate secondary prevention and an active and healthy lifestyle in patients with a TIA or minor stroke.
4. To investigate whether increased physical activity decreases cognitive impairment in patients after TIA or minor stroke.
We expect to only achieve our first goal in this pilot. For the other goals we only expect to demonstrate a non-significant improvement in the intervention group in comparison to the control group. If this pilot proves to be feasible and not too demanding for the patient we will start a larger trial with sufficient power to achieve the other goals.

Study design

We propose a single-blind, randomized controlled single centre pilot trial with an inclusion period of 3 months and a follow-up period of 1 year. Patients, who have recently suffered a TIA or minor stroke, will be asked to participate in the study. 20 patients will be included. Patients will be randomly assigned to two intervention groups; group A, a multidisciplinary chronic poststroke care during one year and group B, a combined multidisciplinary poststroke care program and a physical activity program. Patients in group A and B will be seen in the outpatient clinic at least every 3 months. Patients in group B will also participate in a physical activity program, which consists of an aerobic exercise program of 8 weeks and follow-up care under supervision of a physiotherapist.
Outcome measures for all groups will be assessed at baseline 4 weeks after the event and after 3 and 12 months follow-up. This assessment consists of filling out questionnaires about physical activity, medication adherence, quality of life, fatigue, depression and satisfaction with care, a venipuncture to measure

the cholesterol level, a blood pressure measurement, a neuropsychological assessment, a maximal exercise test and physiotherapy assessment.

Intervention

Patients in group A and B will be seen in the outpatients clinic regularly. These appointments are multidisciplinary with participation of physicians, stroke-nurses, physiotherapists and dietitians. The goal of these appointments are optimising secondary prevention by adjustment of medication and promoting a healthy lifestyle. Medication adjustment will be done by a neurologist (in training), using a stepwise protocol. During these visits an active participation of the patient is requested and selfmanagement will be promoted. To promote selfmanagement we will use the 'motivational interviewing' method, a patient directed, directive method which increases the intrinsic motivation for behaviour change by exploring and solving ambivalence. Patients will visit the outpatient clinic 4 and 12 weeks and 6, 9 and 12 months after the event. Patients in group B will also participate in a physical activity program, which consists of an aerobic exercise program of 8 weeks and follow-up care by physiotherapist. The exercise program consists of aerobic exercise and strength training, 3 times per week during 8 weeks. After this program the patient will be seen in a follow-up care program by the physiotherapist to maintain an active lifestyle. Patients will be seen by a cardiologist and pulmonologist prior to starting with the physical activity program to exclude cardiac and pulmonary contraindications.

Study burden and risks

Outcome measures will be assessed on three occasions during the one 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 cardiopulmonary checklist with the patient. If necessary the patient will be seen by the cardiologist and pulmonologist prior to performing the test. There is always a pulmonary laboratory worker present who is trained in recognising 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

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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 week 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
Operation immediately after TIA or minor stroke
(cardiac or pulmonary) Contraindications for physical activity

Disease with assumed inability to perform physical activity
Dementia

Study design

Design

Study type: Interventional

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-06-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
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	NL31583.029.10