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

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21582

Bron
NTR

Verkorte titel
MoveIT

Aandoening

stroke
TIA
physical exercise
beroerte
lichaamsbeweging

Ondersteuning

Primaire sponsor: Sint Lucas Andreas Ziekenhuis
Overige ondersteuning: Innovation fund Sint Lucas Andreas Ziekenhuis
Stichting Roomsch Catholijk Oude Armen Kantoor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-05-2012
Aantal proefpersonen:	120
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	06-03-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39313
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A