

The effect of a graded physical training program on fatigue after stroke.

No registrations found.

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

Summary

ID

NL-OMON25392

Source

Nationaal Trial Register

Brief title

-

Health condition

ENG: stroke, fatigue, post-stroke-fatigue, graded physical training

NL: beroerte, vermoeidheid, post-stroke-fatigue, gradueel opgebouwde training.

Sponsors and support

Primary sponsor: Avans Plus Hogeschool

Name: E.A.L.M. Tolenaar-Molenaar, MSc.

Adress: Heerbaan 14-40, 4817 NL, Breda

Source(s) of monetary or material Support: -

Intervention

Outcome measures

Primary outcome

Primary outcome measures are:

- Fatigue as measured by the CIS-f (Checklist Individual Strength subscale fatigue) and FSS-7 (Fatigue Severity Scale-seven item version)

Secondary outcome

Secondary outcome measures are:

- Strength as measured by handheld- dynamometer and sit-to-stand test.
- Endurance as measured by the six minute walk test (6MWT)

Study description

Background summary

The objective of this study is to evaluate the effect of a graded physical exercise program on fatigue as measured by the CIS-f and FSS-7.

Participants follow an 8-week physical training program in which strength and endurance are gradually increased according to the Dutch guideline for stroke patients.

Study objective

The hypothesis is that a graded physical exercise program in which strength and endurance are trained have a positive effect on fatigue after stroke measured with the CIS-f (Checklist Individual Strength subscale fatigue) or FSS-7 (Fatigue Severity Scale - seven item version)

Study design

Patients will be assessed at:

T0 --> enrolment (primary and secondary outcome measures)

T1 --> after 4 weeks training (primary outcome measures)

T2 --> after 8 weeks training (primary and secondary outcome measures)

Intervention

The participant will receive an 8-week physical training program in which strength and endurance gradually are increased according to the Dutch Guideline for stroke-patients.

The participant will train under supervision of a licensed physiotherapist twice a week.

Contacts

Public

Stationsstraat 17

Lian Heijnen
Heythuysen 6093 BJ
The Netherlands
0475-491876

Scientific

Stationsstraat 17

Lian Heijnen
Heythuysen 6093 BJ
The Netherlands
0475-491876

Eligibility criteria

Inclusion criteria

The inclusion criteria are:

- Stroke patients with FFS-7 ≥ 4 or CIS-F ≥ 40
- The stroke occurred at least 6 months ago
- The patient is >18 years old
- The patient speaks Dutch and can follow verbal instructions
- Patient is twice a week available for training in the physiotherapists practice.

Exclusion criteria

The exclusion criteria are:

- The patient has a psychiatric disorder (diagnosed according to DSM-IV)
- The patient has a severe communication disorder.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	08-10-2015
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion	
Date:	28-10-2015
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	NL5383
NTR-old	NTR5485
Other	METC Atrium-Orbis-Zuyd : 15-N-138

Study results

Summary results

-