Uit balans

No registrations found.

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

Summary

ID

NL-OMON22817

Source
NTR

Health condition

stroke, stroke patients, dynamic supported standing practice, standing-therapy, standing-balance training, physical therapy, neurological rehabilitation, balance, CVA

Sponsors and support

Primary sponsor: Daniëlle Vreugdenburg
Source(s) of monetary or material Support: Daniëlle Vreugdenburg

Intervention

Outcome measures

Primary outcome

Sit and standing balance measured with the Berg Balance Scale (BBS) and the Trunk Control Test (TCT)

Secondary outcome

Muscle strength of the lower extremity measured by the Motricity Index (MI), walking skills measured with the Functional Ambulation Category (FAC) and the independence on activities of daily living measured with the Barthel Index (BI)

Study description

Background summary

Objective: To evaluate dynamic supported standig versus conventional balancetraining performed by patients with subacute stroke.

Design: pilotstudy

Setting: Geriatric rehabilitation centre

Participants: Non-ambulatory participants in the subacute phase after stroke

Intervention: Usual care that includes either balancetraining in a dynamic standing frame (intervention group) or conventional balancetraining (control group) for 6 weeks.

Main measures: Preliminary effectiveness was assessed with the Trunk Control Test and the Berg Blance Scale (primary outcome). Other measures of physical functioning are Barthel Index, Motricity Index of lower extremiy and the Functional Ambulation Category.

Recruitment in the Netherlands.

Study objective

According to the current Dutch guidelines it is advised to train task-specific and goal-driven with stroke patients. This shows to be almost impossible with a lot of stroke patients in the early subacute phase, especially with the severely affected ones. Therefore only training in function remains. An essential part of this is to practice balance. The improvement of balance achieved by conventional physical therapy treatment are limited. The purpose of the study is to examine the effect of balance training with a dynamic supported standing frame compared to conventional physical therapy treatment on severely affected subacute stroke patients.

Study design

T(0) intake

T(1) after 8 weeks of treatment

Intervention

Intervention: balance training with the dynamic supported standing frame

Control: conventional balance training within physical therapy treatment

Contacts

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Eligibility criteria

Inclusion criteria

Trunk Control Test <100, Functional Ambulation Category ¡Ü 2, being able to stand in the dynamic supported standing frame for at least 15 minutes

Exclusion criteria

Different diagnosis than stroke, more than three month after stroke, medically unstable, Glasgow Coma Scale <11, height <150 cm or >200 cm, weight >120 kg, vision disorder, aphasia, cognitive problems making the patient unable to understand instructions or giving informed consent, musculoskeletal problems of the lower extremity limiting standing or walking (e.g. fractur)

Study design

Design

Study type:	Interventional

Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-10-2017
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-10-2017
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	NL6589
NTR-old	NTR6763
Other	METC : 17N140

Study results