Recovery of walking ability using a robotic device.

Gepubliceerd: 21-12-2011 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON22522

Bron
NTR

Verkorte titel
REWARD

Aandoening

Recovery of walking ability and strength of the lower limbs after stroke

Ondersteuning

Primaire sponsor: VU University Amsterdam
Overige ondersteuning: Dutch Heart Foundation (Hartstichting 07.21)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Walking speed, measured with the 10-m walking speed test.

Toelichting onderzoek

Achtergrond van het onderzoek

The primary objective of the study was to investigate the effectiveness of Locomat training on locomotor performance, participation and quality of life. The study consisted of a randomised clinical trial for stroke patients and further aimed to assess the time course of effects, not only during the training period, but also during follow-up after cessation of the training. Patients, aged from 18 yrs, with left or right hemiparesis as a result of first ever-stroke who were incapable of walking unsupervised were assigned to either a control group or an experimental group. All patients (experimental as well as control) received similar standard occupational and physical therapy care, except for the gait training module which is part of the rehabilitation program. The experimental group received a specific (gait) training program consisting of 2 weekly (1 hour per training) robot-assisted treadmill training sessions with a Lokomat robotic gait orthosis aimed at increasing duration of walking in the device to 45 minutes per session, whereas the control group received conventional physical therapy. Outcome measures for functional ability were walking speed, time to perform "get-up-and-go" test; score at Berg Balance Scale; Functional Ambulation Categories-score; Rivermead Mobility Index; and Brunnstrom Fugl-Meyer. Scores at the questionnaires SIS and SF-36 were used for assessment of quality of life and scores at the SIP-68 were used for assessment of social participation. Study parameters were assessed at baseline, after intervention (8 weeks), after 24 weeks and after 36 weeks.

Doel van het onderzoek

The general hypothesis of the study is that robot-assisted treadmill training with will lead to greater improvements of functional outcome measures of gait performance, social participation and quality of life in stroke patients than the regular care.

Onderzoeksopzet

1. Pre-intervention (wk 1);

2. Post-intervention (wk 10);

3. 24 wks. after start intervention (wk 24);

4. 36 wks. after start intervention (wk 36).

Onderzoeksproduct en/of interventie

8 weeks: 3.5 hours/week, duration matched.

Robot assisted training group: Robot asssited treadmill training using the Lokomat combined with convention physical therapy.

Control group: Conventional physical therapy.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Minimum age of 18 yrs;

2. Hemiparesis (at least of lower limb) as a result of a first ever stroke;

3. Patients must be incapable to walk unaided.

Subjects who are inpatients of the Rehabilitation Centre will start with the training as soon as

they would normally start with the rehabilitation program.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Medical complications such as unstable hypertension, arrhythmias and unstable cardiovascular problems;

2. Severe skeletal problems such as osteoarthritis of the lower limbs;

3. Severe cognitive and/or communicative problems, preventing ability to follow verbal instructions;

4. Earlier neurological and/or psychiatric problems; other problems that would limit the ability to perform the requested tasks;

5. Contra-indications for electrical stimulation (unstable epilepsy, cancer, skin abnormalities, pacemaker).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-03-2008
Aantal proefpersonen:	80
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-12-2011
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3062
NTR-old	NTR3210
Ander register	Dutch Heart Foundation (Hartstichting) : 07.21
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A