Optimizing intermanual transfer effects.

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Type and intensity of the tasks trained influence the training effects while using a myo-electric prosthesis.

Ethische beoordeling	Positief advies
Status	Anders
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22250

Bron
NTR

Aandoening

Upper extremity, Prothesis, Simulators, Motor skill learning, Training tasks, Spacing

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: Revalidatiefonds, Fonds Nuts Ohra, Stichting Beatrixoord, Stichting OIM

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Grip force control: Mean deviation of the asked force in N;
2. Reaching: Mean deviation of the straight path towards the aim in mm;
3. Grasp: Shape of the grasp profile; plateau duration in s;
4. Movement time: Time taken to execute the movement in s.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

To improve the rate of use of prosthetic devices in adults with an upper limb amputation intermanual transfer might be helpful. Intermanual transfer is the ability to transfer motor skills from one, trained side to the other side (Hicks, 1983). This can be used in upper limb amputees by training the unaffected arm while waiting for the prosthesis to be fitted. Especially because it is assumed that training starting early after the amputation will lead to better acceptance and improved prosthetic handling (Malone et al., 1984). Due to intermanual transfer, the prosthetic skills of the affected arm will then improve. Intermanual transfer effects were demonstrated to be present in myo-electric (Romkema, Bongers, & van der Sluis, 2013) and body-powered prosthesis use (Weeks, Wallace, & Anderson, 2003). However, it is unclear how the training program should be like to obtain the largest effects. First, the question rises which tasks the training program should contain to lead to the largest effects of intermanual transfer. Second, it is unknown how the training should be spaced over time for the best results.

Objective:

To compare 1) different training tasks and 2) different training intensities to be able to measure which training has the largest effects. And, 3) whether the effects of this training can also be made visible in patients.

Study design:

Experiments 1 and 2 are non-blinded randomized trials, experiment 3 is a case series.

Study population:

(1) 60 non-amputated adults; (2) 36 non-amputated adults; (3) 4 amputees who will start to use a myo-electric prosthesis for the first time.

Intervention:

In experiment 1 and 2 in total eight groups of 12 participants train to use a prosthetic simulator for 20 min during 5 days. In experiment 3, four patients with an amputation train (5 times 20 min) with the prosthetic simulator on the unaffected arm. The prosthetic simulator mimics the functioning of a real prosthesis but can be worn by able-bodied participants and at the sound side of an amputee patient. The prosthesis simulator places a prosthetic hand in front of the sound hand.

Main study parameters/endpoints:

1. Grip force control: mean deviation of the asked force in N;

2. Reaching: mean deviation of the straight path towards the aim in mm;

3. Grasp: shape of the grasp profile; plateau duration in s;

4. Movement time: time taken to execute the movement in s;

5. Initiation time: time between the starting signal and the actual start in s.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

All participants will use the prosthetic simulator. This simulator mimics a real prosthetic device and can be worn over a sound arm. Because of the use of this simulator we are able to test more participants than only the few recently amputated patients. Importantly, all the measurements are non-invasive and the use of a prosthetic simulator is not different from wearing a regular prosthesis. Therefore, the risks associated with participation can be considered negligible and the burden can be considered minimal.

Doel van het onderzoek

Type and intensity of the tasks trained influence the training effects while using a myo-electric prosthesis.

Onderzoeksopzet

The first experiment will take place in April, May, June, the second experiment in august and september. The patients will be measured during the whole period.

Onderzoeksproduct en/of interventie

Pretest-posttest intervention. Participants in the experimental group will train different tasks

or on different intensities for 5 sessions with a prosthetic device or simulator. Participants in the control group do receive a sham training with the sound hand. Performance on reaching, grasping and force control, will be tested during three tests, a pretest, a posttest and a retention test.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Normal or corrected to normal sight and right-handed.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Neurological problems concerning upper extremity or torso, motor problems concerning upper extremity or torso, earlier experience with a prosthetic simulator and limited sight despite correction.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	15-04-2013
Aantal proefpersonen:	64
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-03-2013
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40603
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3725
NTR-old	NTR3888
CCMO	NL43335.042.13
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON40603

Resultaten

Samenvatting resultaten
N/A