Optimizing intermanual transfer effects.

No registrations found.

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

Summary

ID

NL-OMON22250

Source
Nationaal Trial Register

Health condition

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

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: Revalidatiefonds, Fonds Nuts Ohra, Stichting Beatrixoord, Stichting OIM

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

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

Study description

Background summary

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.

Study objective

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

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

Normal or corrected to normal sight and right-handed.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	15-04-2013
Enrollment:	64
Type:	Unknown

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-03-2013
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40603
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

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

Study results

Summary results
N/A