

Simulators and upper limb prostheses.

No registrations found.

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

Summary

ID

NL-OMON21697

Source

Nationaal Trial Register

Health condition

Bimanual transfer, upper limb prosthesis, simulators.
Bimanuele transfer, armprotheses, simulatoren.

Sponsors and support

Primary sponsor: UMC Groningen

Source(s) of monetary or material Support: ZonMW

Intervention

Outcome measures

Primary outcome

During three tests, pretest (day 1), posttest (day 5) and retention test (day 11) the movement and initiation time of three functional activities are measured using E-prime. With two deformable objects the force control is measured (the amount of pressure applied).

Secondary outcome

N/A

Study description

Background summary

People with an upper extremity amputation often choose to have fitted a prosthesis to restore the functionality for as best as possible. But the rejection rate of prosthetic devices is high, mainly due to a low degree of functional use (Biddiss & Chau, 2007; Dudkiewicz, Gabrielov, Seiv-Ner, Zelig, & Heim, 2004; Kyberd, Davey, & Morrison, 1998; Plettenburg, 2002). Functional use can be enhanced by training (Carter, Torrance, & Merry, 1969; Lake, 1997; Weeks, Wallace, & Anderson, 2003). To achieve maximum success in prosthetic use it is important to start to train in the first weeks after the amputation (Atkins, 1992; Dakpa & Heger, 1997; Gaine, Smart, & Bransby-Zachary, 1997). However, in these initial stages of rehabilitation the wounds are not healed yet and the prosthesis is not finished. To be able to start training within these initial stages, we propose to use the unaffected limb. With an upper limb prosthetic simulator, as developed earlier in Groningen, training can start with the unaffected hand. It is hypothesised that training the unaffected hand results in a higher starting level and faster learning of the affected hand. This effect is called 'transfer of learning' (Hicks, Gualtieri, & Schoeder, 1983; Karni et al., 1998; Kumar & Mandal, 2005; Lee, Hinder, Gandevia, & Carroll, 2010; Mier & Petersen, 2006; Pereira, Raja, & Gangavalli, 2011).

If we indeed establish that this transfer has effect on learning to use a prosthesis, then this might help the rehabilitation after an amputation of the upper limb to become faster and more efficient.

Study objective

After training one arm with a prosthetic simulator it is expected that the other arm will improve.

Study design

First experiment 15-aug-2011;

Second experiment 19-sept-2011;

Third and fourth 1-oct-2011.

Intervention

The training group gets a training with a prosthetic simulator for half an hour on 5 consecutive days, while the control group does not get any intervention. The training consists of the Southampton Hand Assessment Procedure.

In three tests, for both groups, the execution of tasks is analyzed.

Contacts

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Eligibility criteria

Inclusion criteria

Healthy participants: Normal or corrected to normal sight, righthanded.

Experienced prosthetic users: Normal or corrected to normal sight, unilateral forearm amputation, experience with a myo-electric prosthesis.

Novice prosthetic users: Unilateral forearm amputation.

Exclusion criteria

1. Limited sight despite correction;
2. Motor problems concerning measured upper extremity;
3. Experience with the prosthetic simulator.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	15-08-2011
Enrollment:	116
Type:	Anticipated

Ethics review

Positive opinion	
Date:	31-08-2011
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38367
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2907

Register

NTR-old

CCMO

ISRCTN

OMON

ID

NTR3053

NL35268.042.11

ISRCTN wordt niet meer aangevraagd.

NL-OMON38367

Study results

Summary results

N/A