Clinical application of simulators when learning to use upper limb prostheses

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Interventional

Summary

ID

NL-OMON38367

Source
ToetsingOnline

Brief title
Simulators and upper limb prostheses

Condition

- Musculoskeletal and connective tissue disorders congenital
- Bone and joint therapeutic procedures

Synonym
Upper limb amputation

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Learning, Prosthesis, Upper limb

Outcome measures

Primary outcome

See the research protocol.

Secondary outcome

Not applicable.

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. About 30% of upper extremity amputees do not use their prosthesis at all due to a low degree of functional use (Biddiss & Chau, 2007; Dudkiewicz et al., 2004; Kyberd et al., 1998; Plettenburg, 2002). The functional use of upper extremity prostheses is not only determined by its function, the technical possibilities, but also by its functionality, the way the amputee is able to handle the prosthesis. The proposed innovation intends to enhance the functionality to improve the use of prostheses and with that to make rehabilitation more successful.
It is found that it is of great importance to start to train in the first month after the amputation to achieve maximum success in prosthetic use (Atkins, 1992; Dakpa & Heger, 1997; Gaine et al., 1997). But in this period often the wounds are not healed yet and the prosthesis is not finished. To be able to start to train within these weeks, a prosthetic simulator on the unaffected limb could be used. With an upper limb prosthetic simulator training can start with the unaffected hand. Because of a transfer of learning effect a higher starting level can be reached at the time the prosthetic training is started on the amputated side.
A prosthesis simulator is an upper limb prosthesis that can be applied to a sound arm. With the prosthesis simulator the effects of a myo-electric prosthesis can be mimicked. In myo-electric prostheses the hand is opened and closed by a motor that is activated by electrical signals produced by the muscles. The simulator can be used in the same way. It is applied over the arm, where the prosthetic hand is placed in front of the sound hand (see figure 1 of the research protocol). Therefore the training with the simulator is comparable.
In literature it is shown that motor skills learned with one arm are effecting

the execution of the same skills of the other arm. (Hicks et al., 1983; Karni et al., 1998; Kumar & Mandal, 2005; Lee et al., 2010; Mier & Petersen, 2006; Pereira et al., 2011). This transfer of learning effect can be used in the rehabilitation after an amputation. After training the unaffected hand with the simulator it is expected that the affected hand has a higher starting level and that the skills are improving faster. In this way the sound arm can be used to train the prosthesis simulator, while improvement of the other arm is expected due to the transfer of learning effects.

Study objective

The objective of this study is to determine the application of the prosthesis simulators and the bimanual transfer effects in the existing rehabilitation programs for patients who will obtain an upper limb prosthesis.

At first it needs to be revealed if transfer of learning effects are presented in the use of a prosthetic simulator. Bimanual transfer effects are found in several simple and some complex tasks ((Hicks et al., 1983; Karni et al., 1998; Kumar & Mandal, 2005; Lee et al., 2010; Mier & Petersen, 2006; Pereira et al., 2011; Weeks et al., 2003). Although it is has never been applied to a myo-electric prosthetic simulator. Therefore, our first goal is to analyze the transfer effects in healthy adults after training with the simulator.

The next step is to determine if the transfer effects are not only presented in the usage of the prosthesis simulators, but also in the real prostheses. For the rehabilitation it is of great importance to establish if the effects found in prosthesis simulators are generalizable to the prostheses. Here for, first it is analyzed if experienced prosthetic users are more skillful in using the prosthesis simulator on their sound arm then the able-bodied participants. This effect is expected because of the transfer effects from the well trained amputated limb towards the prosthesis simulator on the sound arm. As far as we know it is never described how prosthesis users execute activities with a tool the unaffected arm.

Finally, it will be revealed if the transfer effects are presented in patients who will obtain their first myo-electric prosthesis. We expect that patients who will train with a prosthesis simulator develop skills to be able to perform better using the prosthesis once it is finished. This means that patients can start to train earlier in the rehabilitation process, what can lead to more successful use of the prosthesis. If the transfer effects are determined, this study results will have important consequences for the early rehabilitation after an upper limb amputation.

Study design

Four experiments, each with their own design are presented (See table 1-4 from the research protocol). In all experiments the same tests and training are used.

The goal of the first experiment is to test if transfer of learning effects are measurable in able-bodied adults using the simulator. The participants in the experimental group learn to use the simulator on one hand (training hand) while transfer effects are measured on the other (test hand). The control group only performs the tests, to analyze the added effects of the training.
The learning is divided over five days to mimic a real learning process in rehabilitation. It is found that the distribution of the training over more days is important for the consolidation of learning (Park & Shea, 2003; Penhune, 2004; Savion-Lemieux & Penhune, 2005; Siengsukon & Boyd, 2009). As such, training on several days is also important for the transfer of learning. Pereira (2011) found improvement in dexterity skills in the untrained limb after practicing with low intensity (20 min a day) spread over 5 days.
We will use the Southampton Hand Assessment Procedure (SHAP) for training (Metcalf, 2008). With the SHAP we can offer a standardized training procedure with sufficient variation in tasks (26) in order to be able to promote strong learning (Schmidt 1999). This variability will improve skill acquisition, retention and transfer (Stokes 2008). Half of the patients will train their dominant hand and half will train their non-dominant hand.
A pretest, posttest and retention test will be performed to determine if there are learning effects and if these will remain. Only when there are significant results we will continue with the other experiments.

In the third experiment experienced adult and paediatric prosthetic users will perform the same tests as the able-bodied participants, with the simulator on the sound arm. With the results of this experiment we will reveal general principles of transfer of learning in real prosthetic use. It is expected that while using the prosthesis there is a bimanual transfer effect. As such, we expect it will be easier for experienced prosthesis users to execute the tasks with the simulator. As far as we know it has never been reported before how a prosthetic user performs activities with a tool on the sound hand.

The last part aimes to reveal generalization of the findings to the patients who intend to wear a myo-electric prosthesis for the first time. The design is the same as in experiment 1, except that the pretest will not be executed because the prosthesis will not be available at that time.

Intervention

See the research protocol.

Study burden and risks

Execution of the tests from the SHAP with the prosthesis simulator does not have any risks.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

48 able-bodied adults.
4 adult patients with an unilateral forearm amputation and an indication for a first myo-electric prosthesis.
12 experienced prosthetic users.

Exclusion criteria

Patients: an amputation at a different level than a forearm amputation
Able-bodied persons: limited sight, limited hand or arm function

Study design

Design

Study type: Interventional

Intervention model: Other

Allocation: Non-randomized controlled trial

Masking: Open (masking not used)

Primary purpose: Treatment

Recruitment

NL
Recruitment status: Recruitment stopped

Start date (anticipated): 05-09-2011

Enrollment: 64

Type: Actual

Medical products/devices used

Generic name: upper limb prosthesis simulator

Registration: No

Ethics review

Approved WMO
Date: 05-08-2011

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO
Date: 30-10-2012

Application type: Amendment

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21697
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL35268.042.11
OMON	NL-OMON21697
OMON	NL-OMON28604