Clinical application of simulators when learning to use upper limb prostheses in children

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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-OMON36164

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: Children, Learning, Prosthesis, Upper limb

Outcome measures

Primary outcome

The time of execution of each task in the pretest, posttest and retention test

is measured by having the participant pressing a timer button before the

execution of the task until an auditory tone and after executing the task. This

will give the reaction time, the time between the auditory tone and the release

of the button, as well as the movement time, the total time between the release

of the button and the return to the button at the end of the trial.

In the two force control tasks the extent to which objects are compressed is

measured. This can be translated to the amount of force applied. Since the

instruction is to not compress the object, in this task the force control is

measured.

Secondary outcome

Not applicable.

Study description

Background summary

Children with an upper limb deficiency often choose to have fitted a prosthesis to improve functionality. Despite all technical developments and improvements in upper extremity prostheses, the rejection rate of the prosthetic devices is high (Meurs, Maathuis, Lucas, Hadders-Algra, & van der Sluis, 2006; Postema, van der Donk, van Limbeek, Rijken, & Poelma, 1999; Scotland & Galway, 1983). 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. As has been shown, this latter aspect can be enhanced by training (Carter et al., 1969; Lake, 1997; Weeks et al., 2003). Our hypothesis is that prosthetic training can be improved by using the concept of *transfer of learning*. Transfer of learning is the finding that a motor skill learned at one side of the body transfers to the other side of the body. As such, the level of skill of the untrained side of the body improves. This concept has been extensively studied (Hicks et al., 1983; Karni et al., 1998; Kumar & Mandal, 2005; Lee et al., 2010; Mier & Petersen, 2006; Pereira et al., 2011), but not in the use of myo-electric upper limb prostheses. As such, we propose to start prosthetic training in the unaffected limb. With an upper limb prosthetic simulator, as developed earlier in Groningen, the unaffected arm can be trained. With a prosthetic simulator it is possible to mimic the effects of a myo-electric prosthesis because it*s functioning is similar to the functioning of a prosthesis. A prosthetic hand can be opened and closed with a motor driven by electrical signals that are produced by muscle activation. The simulator is placed over the arm, and the prosthetic hand is placed before the sound hand (see figure 1 of the research protocol) and then operates in the same way as the prosthesis. The training with the simulator is therefore comparable to the training with the myo-electric prosthesis. By using the prosthetic simulator in this study it can be shown whether the effects of transfer of learning are present in healthy participants. Transfer of learning in adult amputees will be investigated in a separate research project executed by our team. If the transfer of learning is detectable in adults, the next step is to reveal if these effects are also present in children. Until now it is unclear what the effects and application of transfer of learning in children are. Literature states that in children the transfer of learning increases from 5 years old on (Byrd et al., 1986; Parlow & Kinsbourne, 1989; Uehara, 1998). The first step, therefore, is to reveal if the transfer of learning effects are present in children between 5 and 7 years old. By using able-bodied children we do not need to bother children with an amputation with research and we will have the ability to study more participants. It is important that we study transfer effects in the execution of a complex task. The results of the study in healthy children will give information about the development of transfer of learning at a young age. Thereby, when the effects are found to be present, this can have important consequences for children with acquired upper limb amputation or a congenital upper limb deficiency.

In case of congenital deficiencies there is no need to start prosthetic training within a short period of time. However, the transfer of learning effect might also be beneficial to children, because if transfer of learning takes place, the child can start at a higher functional level when the actual prosthesis is delivered. Apart from that, the training with a simulator using the unaffected arm provides information on the capacities of a child to handle a myo-electric prosthesis. As a consequence, the rehabilitation process might be shorter and more satisfactory to the child, which may diminish the rejection rate of these expensive devices.

Study objective

The objective of this study is to establish the effects of transfer of learning in children with upper limb deficiencies after practising with an upper limb prosthetic simulator.

In children, transfer of learning effects have hardly been studied. The scarce literature, which is mainly based on the execution of simple tasks, states that transfer of learning can only be detected from 5 years on (Uehara, 1998). While the child gets older the transfer of learning effects seem to improve (Byrd, Gibson, & Gleason, 1986; Parlow & Kinsbourne, 1989).
Prosthetic simulators have never been used in children before. Training with a simulator before the actual prosthesis is delivered may have the advantage of the transfer of learning effects, which is subject of the present study.
Moreover, using the simulator might give children and their parents an idea of the possibilities of a real myo-electric prosthesis. Furthermore, when a child trains his unaffected arm with a simulator, the rehabilitation team gets an impression of the capacities of the child to handle a myo-electric prosthesis.
If the child*s capacities are adequate, the team has more evidence that a myo-electric prosthesis is the right choice for the child. This can reduce the high rejection rate (Meurs, Maathuis, Lucas, Hadders-Algra, & van der Sluis, 2006; Postema, van der Donk, van Limbeek, Rijken, & Poelma, 1999; Scotland & Galway, 1983) in children.
With this project the first step is made by analyzing the transfer of learning effects in able-bodied children.

Study design

There is a pre-post design used, where half of the group trains in between (see table 1 of the research protocol).

To measure the transfer of learning effects, a pretest, posttest and a retention test will be performed. At the start of the experiment, the functional level of the *test hand* (which resembles the affected hand) will be measured in all children (pretest). The children are pseudo-randomly divided in a control and an experimental group, in such a way that the amount of boys and girls is equal in both groups. Then the children that form the experimental group will train the *training hand* (which resembles the unaffected hand) using the simulator. The other half of the children comprises the control group. These controls do not train with the simulator. After five days, the functional level of the *test hand* will be measured again in all experimental and control children (posttest). After one week, all children will be measured again to evaluate the consolidation of the transfer of learning effects (retention test). With a retention test, the lasting of the learning effects can be determined (Schmidt & Lee, 2005).

Intervention

The training will be performed over five days to mimic a real learning process in rehabilitation. It is found that the distribution of training over several days is important for the consolidation of learning (Park & Shea, 2003; Savion-Lemieux & Penhune, 2005; Siengsukon & Boyd, 2009). Furthermore, Pereira et al. (Pereira et al., 2011) found improvement in complex dexterity skills in the untrained limb after practicing with low intensity (20 min a day) spread over 5 days. As such, training on several days seems to be important for the transfer of learning as well.
For the training the Southampton Hand Assessment Procedure (SHAP) will be used (see also paragraph 7.3 from the research protocol). 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 & Lee, 2005). This variability will improve skill acquisition, retention and transfer (Stokes et al., 2008). Half of the children will train their dominant hand and half will train their non-dominant hand.

Study burden and risks

The burden is expected to be minimal. The children will execute three tests and half of them is training for five days. It is expected that the children like to execute the tests and training. Execution of the test and the tasks 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
Children (2-11 years)

Inclusion criteria

48able-bodied right- handed children (5-7 years old)

Exclusion criteria

Limited sight, limited hand or arm function

Study design

Design

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

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-11-2011
Enrollment:	48
Type:	Actual

Medical products/devices used

Generic name:	Upper limb prosthesis simulator
Registration:	No

Ethics review

Approved WMO Date:	01-09-2011
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL37362.000.11