Optimizing the intermanual transfer effects after training with a prosthetic simulator

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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-OMON40603

Source
ToetsingOnline

Brief title
Optimizing intermanual transfer effects

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: Fonds Nuts Ohra;Revalidatiefonds;Stichting

OIM;Stichting Beatrixoord

Intervention

Keyword: Intermanual transfer, Prosthesis, Training, Upper limb

Outcome measures

Primary outcome

- Grip force control: mean deviation of the asked force in N is measured in the grip force control tasks.

- Reaching: mean deviation of the straight path towards the target in mm is measured in the reaching task.

- Grasp: length of plateau phase (maximal hand opening) in seconds is measured in the grasping task.

- Movement time: time taken to execute the movement in seconds is measured in the functional task.

- Initiation time: time between the starting signal and the actual start in seconds is measured in the functional task.

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. Nevertheless, 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. In an earlier study of our research group is shown that prosthetic skills can be improved when using intermanual transfer {{136 Romkema,S. 2012}}.

Intermanual transfer implies that when you learn a motor task with one arm, not only that arm improves, but also the arm at the other side becomes better in the specific task (Hicks et al., 1983; Karni et al., 1998; Kumar & Mandal, 2005; Lee et al., 2010; Mier & Petersen, 2006; Pereira et al., 2011). The untrained side thus benefits from the trained side. The effect of intermanual transfer is shown to be present in prosthetic use, as well in body-powered (Weeks et al., 2003) as in myo-electric prosthesis (Romkema et al., 2012). We showed that after training of the *unaffected* side using the simulator, the level of skills at the start of the prosthetic use with the *affected* side was increased. This effect can be useful in rehabilitation after an upper limb amputation, because the training can be started earlier.

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, in our last study (NL 35268.042.11) we used a prosthetic simulator on the unaffected limb. 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. With an upper limb prosthetic simulator training can start with the unaffected hand. Because of an intermanual transfer effect a higher starting level can be reached at the time the prosthetic training is started on the amputated side.
From our earlier study we know that after training with the simulator on one arm, the movement times in the other arm decreased. Though, until know it remains unclear what this training should be like. What tasks will give the largest results and what time intervals should be in between the training sessions?

Study objective

The objective of this study is to determine the optimal myo-electric prosthesis training for obtaining the largest transfer effect. Here fore we plan to execute three experiments.

At first it needs to be revealed which trainingtasks leads to the largest transfer of learning effects in using prosthetic simulators. We use four different training groups. Three groups train each one of the skills necessary

to control a prostheses (reaching, grasping and force control). The last group trains a combination of all three training tests. The findings will be compared with a control group, that did not follow a training with the prosthetic simulator, though will execute the tests. Therefore, our first goal is to analyze the transfer effects of different training tasks in prosthetic simulator use in healthy adults.

The next step is determining the optimal spacing of training with a myo-electric prosthetic simulator. The same experiment as described above will be executed, though with different time intervals between the training sessions. With this the interval with the best effect can be found. There is a lot of research done on the intensity of the training programs, though often this is done within 24 hours. Our study will focus on a rehabilitation-like setting and will therefore be three days long. With this, only a small part of the research focuses on motor skills. Therefore our aim is to find out how long the interval needs to be in myo-electric prosthetic use to reach, until two weeks after the training, the largest effect.

Finally, it will be revealed if the transfer effects are not only present in prosthetic simulators but also in real prostheses. For rehabilitation it is of great importance to find out if the effects found in prosthetic simulators are also present in prosthetic users. At the moment a study on the intermanual transfer effects in a small amount of patients using a myo-electric prostheses (maximal four) takes place NL 35268.042.11). Because in the end our study focuses on these patients we would like to include them in both the study on the tasks as well as on the study on the spacing. De first to patients will follow the training with the tasks that has been shown to obtain the best results. The second two will follow the same training but then with the optimal time interval. De results of these patients can afterward be compared with the patients that did not followed a training and were measured for the earlier study. This is to burden the patient group as less as possible.

Study design

Three experiments, each with their own design are presented (See table 1 and 2 from the research protocol). In all experiments the same tests are used.
The goal of the first experiment is to test with which kind of tasks the intermanual transfer effects are largest in able-bodied adults using the simulator. There will be four experimental groups. The participants in these groups learn to use de simulator on one arm (training arm). The other arm (test arm) is measured to find out if there is an improvement. Each group will train one of the skills necessary to control a prosthesis. The first group trains only the force control, e.g. the control over the amount of activation to prevent an object to be squeezed too hard or to prevent it from dropping. The second group trains only the reaching movements to learn to adapt to the changes in inertia caused by the additional weight. The third group trains reaching movements without the experience of the extra weight of the prosthesis

simulator. In this manner the coordination of the grasping is trained. The training program of the last group consists of all the three prosthetic skills. The found effects will be compared to the sham group (the fifth group) that did not receive any training with the prosthetic simulator, though only with the sound hand and to the control group that just executes the tests. The different training programs all take 20 minutes and are executed on three consecutive days. In our earlier study we found that transfer effects were clearly visible after five days of training, we expect to be able to measure differences in three days, while still mimicking a realistic rehabilitation setting. The measurements consists of a pretest, posttest and retention test (seven days after ending the training), to be able to measure whether there were learning effects and whether these effects remained. All tests consist of the same tasks; functional, grip force control, reaching and grasping tasks, with which we measure whether participants execute the tasks faster, improve their coordination and force control. Half of the participants will train their dominant hand and half will train their non-dominant hand.
In the second experiment we will try to find out what the effect of spacing of the training on the transfer effect is. As found in the literature, for different tasks, the largest effects are found with a period of minimal 24 hours between training sessions. Though, there is not a lot of research done in motor skills and for periods longer than 24 hours. Apart from that, it is shown that the optimal effect depends on the nature of the task and the time of the retention test. For this study we therefore choose to use three different intervals with a minimum of 24 hours. The first group trains daily, the second group trains every second day, the third group trains with two and three days in between the training sessions. The training tasks will be chosen based on the experiment described above; the tasks with the largest effects will be used. Apart from the three tests as in the last experiment, there will be extra retention test. The first retention test takes place on day 10, the second two weeks after the last training session. This will make it possible to show the effects of the different intervals until two weeks after the training.
The last experiment is meant to generalize the results to patients with an upper-limb amputee. For this experiment patients with an amputation that will get a myo-electric prosthesis for the first time will be included. The design of the experiment is comparable to the for the experiments described above, while the most effective design will be used. The pretest will be left out because this is impossible due to the amputation.

Intervention

In experiment 1 in total six groups of 12 participants train to use a prosthetic simulator for 20 min during 5 days. In experiment 1 and 2 in total four groups of 16 participants train to use a prosthetic simulator for 30 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.

Study burden and risks

Performing tasks with a prosthetic 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

136 able-bodied right-handed adults (18-40 years old) with normal or corrected to normal sight.
4 adult patients with an unilateral forearm amputation and an indication for a first myo-electric prosthesis

Exclusion criteria

Able-bodied:(1) Neurological problems concerning upper extremity or torso
(2) Motor problems concerning upper extremity or torso
(3) Earlier experience with a prosthetic simulator
(4) Limited sight despite correction
Patients: amputation at a different level than a forearm amputation

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-06-2013
Enrollment:	140
Type:	Actual

Medical products/devices used

Generic name:	upper limb prosthesis simulator
Registration:	No

Ethics review

Approved WMO

Date:	06-06-2013
Application type:	First submission

Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	05-02-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	15-04-2014
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: 22250
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL43335.042.13
Other	TC3888
OMON	NL-OMON22250