Intermanual transfer using mental imagery in prosthetic training

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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-OMON40668

Source
ToetsingOnline

Brief title
Intermanual transfer using mental imagery

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, Mental imagery, Prothesis, Training

Outcome measures

Primary outcome

- Movement time: time taken to execute the task in s.

- Grip force control: mean deviation of the asked force in N.

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, Gabrielov et al. 2004, Kyberd, Davey 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 (Romkema, Bongers et al. 2013).

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, Gualtieri et al. 1983, Karni, Meyer et al. 1998, Kumar, Mandal 2005, Lee, Hinder et al. 2010, Mier, Petersen 2006, Pereira, Raja 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, Smart 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 functional and force control tasks with the simulator on one arm, the movement times in the other arm decreased. Though the effect is minimal en we would like to enlarge it by using mental imagery.

Study objective

The objective of this study is to determine the surplus value of mental imagery on myo-electric prosthesis training Here fore we plan to execute two experiments.

The goal of the first experiment is to test if intermanual transfer effects of able-bodied adults using the simulator can be increased. There will be two training groups. The participants in these groups learn to use the simulator on one arm (training arm). The other arm (test arm) is tested to find out if there is an intermanual transfer effect. One group will only obtain intermanual transfer training while the other group obtains intermanual transfer training extended with mental imagery. Both training groups will get a functional training and a training focused on force control. The control group receives a sham training not consisting of motor learning. All training programs take 45 minutes per session and are executed on five consecutive days.

In the second experiment, 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 eight) takes place (NL 35268.042.11 and NL 43335.042.13). Because in the end our study focuses on these patients we would like to include them also in this study. These two patients will follow the training where intermanual transfer and mental imagery are compared.

The results of these patients can afterward be compared with the patients that did not followed a training and with patients that trained using intermanual transfer only. These patients were measured in the earlier studies and this is to burden the patient group as less as possible.

Study design

Voor elk van de doelen wordt een experiment uitgevoerd met een eigen design (zie tabel 1-2 uit het onderzoeksprotocol). Voor alle tests worden de zelfde taken en metingen gebruikt.

In het eerste experiment wordt gekeken wat het additionele effect van mental imagery is. Er zijn twee trainingsgroepen en een controle groep. De proefpersonen in de trainingsgroepen leren de simulator aan één hand (trainingshand) te gebruiken. De andere hand (testhand) wordt gemeten om te kijken of hier vooruitgang is. De eerste groep traint intermanuele transfer en mental imagery, de tweede groep traint alleen intermanual transfer en de controle groep krijgt een sham training. De trainingen zijn gericht op functionele en krachtscontrole taken. En alle trainingsprogramma*s worden uitgevoerd gedurende 45 min uitgevoerd op 5 opeenvolgende dagen.

De meetmomenten bestaan uit een een pretest, posttest en een retentietest (zes dagen na afronding van de training), waarmee wordt bekeken of er leereffecten aanwezig zijn en tevens of deze behouden blijven.

Het tweede experiment is bedoeld om bovenstaande resultaten te kunnen generaliseren naar de patiënten. Voor dit deel worden patiënten met een armamputatie die in aanmerking komen voor een eerste myo-electrische prothese geïncludeerd. Het design van het experiment is gelijk aan die van de hierboven beschreven experimenten met uitzondering van de pretest, die wordt weggelaten, omdat deze vanwege de amputatie niet uitvoerbaar is.

Intervention

In experiment 1 , three groups of 16 participants train to use an prosthetic simulator on 5 consecutive days for 45 minutes. One group trains, beside intermanual transfer also mental imagery, where using mirror therapy and motor imagery, movements are learned by imagining these. In experiment 2 patients with an upper limb amputation train the unaffected hand with the prosthetic simulator. The prosthetic simulator mimics a real prosthesis, though can be worn on the sound arm. The prosthetic hand of the simulator is placed in front of the sound hand.

Study burden and risks

Performing tasks with a prosthetic simulator and mental imagery don't 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 right-handed adults, 18 till 40 years old, with normal or corrected to normal sight.
2 adult patients with an unilateral forearm amputation and an indication for a first myo-electric prosthesis.

Exclusion criteria

Neurological problems concerning upper extremity or torso
Motor problems concerning upper extremity or torso
Earlier experience with a prosthesis simulator
Limited sight despite correction
--> This is based on the opinion of the participant;Patients: amputation at a different level than a forearm amputation.
Insufficient knowledge of the Dutch language
Inability to follow instructions
Diseases affecting the joints, nerves or muscles of the non- amputated arm, such as rheumatoid arthritis.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-04-2014
Enrollment:	50
Type:	Actual

Medical products/devices used

Generic name:	Upper limb prosthesis simulator
Registration:	No

Ethics review

Approved WMO

Date:	18-04-2014
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL48028.042.14
Other	NTR (nog geen nummer, gebruiker 16408)