

# Measuring the natural learning processes while learning to use a body-powered simulator prosthesis.

Published: 07-06-2010

Last updated: 04-05-2024

To measure the natural learning processes that take place while learning to use an body-powered upper extremity prosthesis.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Pending
<b>Health condition type</b>	Bone and joint therapeutic procedures
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON32867

### Source

ToetsingOnline

### Brief title

Natural learning processes of body-powered prosthetic simulator.

### Condition

- Bone and joint therapeutic procedures

### Synonym

amputation, amputee

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Rijksuniversiteit Groningen

**Source(s) of monetary or material Support:** Stichting OIM.

## Intervention

**Keyword:** Learning, Prosthetic, Simulator, Upper limb

## Outcome measures

### Primary outcome

Test:

Time of execution of the tests tasks and the scores of these tasks in Index of Functionality.

Training:

Movement kinematics: movement reach time, movement grasp time, velocity of the reach, peak velocity of the reach, symmetry of the velocity profile, hand aperture, plateau phase in the hand aperture, velocity of hand opening and closing, and the timing between the reach and the grasp movement;

Applied grip force;

The pattern of the gaze of the participants: the sequence in which the objects are fixated during a trial.

### 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, but the rejection rate of prosthetic devices is high, mainly due to a low degree of functional use (Biddis and Chau, 2007; Dudkiewicz et al., 2004; Kyberd et al.,

1998; Plettenburg, 2002). This functional use can be enhanced by training (Carter, Torrance and Merry, 1969; Lake, 1997; Weeks, Anderson and Wallace, 2003). We expect that by enhancing the functional use through training, this raises the overall use of prostheses. The training currently given by rehabilitation centre is not evidence-based, but mainly based on own experiences. Therefore, the overall aim of our project is to develop an evidence-based training protocol for upper extremity prostheses, where we focus in particular on body-powered prostheses.

Before an evidence-based training program can be developed, we first have to know how people learn to use their prosthesis. Therefore, the natural learning processes during learning have to be determined. Describing the changes in movement characteristics over learning gives us hints as to where we can focus on in developing the training protocol.

### **Study objective**

To measure the natural learning processes that take place while learning to use an body-powered upper extremity prosthesis.

### **Study design**

Cohort analytic study.

### **Intervention**

One group trains direct grasping, one group trains indirect grasping, one group trains fixating and one group trains a combination of the three tasks.

### **Study burden and risks**

The experiment is non-therapeutic, the participants have to learn to use a simulator during five training sessions and four test days. The measurements are non-invasive. Therefore, the risks associated with participation can be considered negligible and the burden can be considered minimal. In this early stage of discovering natural learning processes we do not want to bother the few patients who have just been amputated. Therefore, we will use body-powered prosthetic simulators, which mimic real prosthetic devices and can be worn over a sound arm. With the use of the simulators we can also test more participants than only the few recently amputated patients.

## **Contacts**

### **Public**

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## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Normal or corrected to normal sight

Right-handed

### Exclusion criteria

Neurological problems concerning upper extremity or torso

Motor problems concerning upper extremity or torso

Earlier experience with a prosthetic simulator

## Study design

## Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Treatment

## Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-01-2010

Enrollment: 32

Type: Anticipated

## Ethics review

Approved WMO

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**

CCMO

**ID**

NL31039.042.09