PROSTHETIC: research in hand prostheses

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In the field of myoelectric upper limb prostheses, a huge gap exists between the mechanical/electrical functions of prosthetic hands and the possibilities of the user to control those (i.e. the human-machine interface). Traditional control (called “...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28964

Bron
Nationaal Trial Register

Verkorte titel
PROSTHETIC

Aandoening

Adults with an acquired amputation or congenital deficiency at the transradial level (including wrist disarticulation) with sufficient surface electromyography (sEMG) signals for using a myoelectric prosthesis. And a control group of able-bodied participants, to establish baseline values.

Ondersteuning

Primaire sponsor: The European Council, University Medical Center Groningen
Overige ondersteuning: The European Council, University College Fryslân, Revalidatiefonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome variable is the Partial Southampton Hand Assessment Procedure (P-SHAP) score (SHAP is a functional test often used in prosthetic research).

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: In the field of myoelectric upper limb prostheses, a huge gap exists between the mechanical/electrical functions of prosthetic hands and the possibilities of the user to control those (i.e. the human-machine interface). Traditional control (called “direct control”, DC) has shown to be non-intuitive, resulting in device abandonment rates in the range of up to 28%, even with state-of-the-art prosthetic hands. To overcome the non-intuitiveness of DC, a form of control based on machine learning algorithms (ML) has been developed. However, until now it remains unclear whether ML control is superior to DC. Moreover, no well-grounded training scheme exists for neither DC nor for ML control, even though it is widely known that quality of training highly affects the satisfaction with prostheses and thus the risk of device abandonment. Serious games (i.e. video games that are fun/engaging to play and at the same time teach the user specific skills) have often been suggested in the literature for myoelectric training with DC and ML control, but controlled studies with prosthesis users are lacking.

Objective: The aim of this experiment is to assess whether training based on serious gaming and conventional methods lead to different functional outcomes for DC and ML control. Moreover, the aim is to find out whether ML control and DC control lead to different functional outcomes.

Doel van het onderzoek

In the field of myoelectric upper limb prostheses, a huge gap exists between the mechanical/electrical functions of prosthetic hands and the possibilities of the user to control those (i.e. the human-machine interface). Traditional control (called “direct control”, DC) has shown to be highly non-intuitive, resulting in device abandonment rates in the range of up to 28%, even with state-of-the-art prosthetic hands. To overcome the non-intuitiveness of DC, a form of control based on machine learning algorithms (ML) has been developed. However, until now it remains unproven whether ML control is superior to DC. Moreover, no well-grounded training scheme exists for neither DC nor for ML control, even though it is widely known that quality of training highly affects the satisfaction with prostheses and thus the risk of device abandonment. Serious games (e.g. video games that are fun/engaging to play and at the same time teach the user specific skills), have often been suggested in the literature for myoelectric training with DC and ML control, but controlled studies with patients are

lacking.

The aim of this experiment is to assess whether training based on serious gaming and conventional methods lead to different functional outcomes for DC and ML control. Moreover, the aim is to find out whether ML control and DC control lead to different functional outcomes.

Onderzoeksopzet

All subjects will be tested twice; during the pre- and posttest. During these moments the primary and secondary outcomes will be measured. Between the test sessions there are 7 training sessions. During these sessions the other outcome measures are recorded.

Onderzoeksproduct en/of interventie

All groups except for the able bodied reference group will go through a similar training- and testing scheme. This training- and testing scheme will take place over the course of ten separate days. On the first day (T0) for all participants (except the reference group) a custom socket will be made using plaster in which the liner containing the electrodes will be placed and on which the Michelangelo hand (Otto Bock, see Methods) will be fitted.

Explanation about the working of the hand will be given after which the participants will go through a pre-training session of 20 minutes. This training day is needed in order to learn the participants about the active modes of the prosthesis and how to change between these active modes. At T1 and T9 all participants can get (re-)acquainted with the hand for 5 minutes. After the five-minute period a test will be performed. On T1 this is the pre-test, on T9 it is the post-test. These two test days are identical except for the questionnaire conducted on T9. This questionnaire evaluates the usability of a device, in our case the prosthetic device. At T2-T8, the participants will conduct a session of 45 minutes consisting of 30 minutes of training and 15 minutes of rest. All days (T0-T9) will be conducted within a period of one month. Participants can decide on the planning of the training sessions except for the time between T8 and T9. In order to prevent wash-out of the training effect, T8 and T9 can only be separated by one day. The control group consists of 10 subjects with two sound hands who will perform several tasks of which the outcomes will be compared to the outcomes of the four main groups on the same tasks. These outcomes will be used as norm scores.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Inclusion criteria are:

- 18 years of age or older

- Upper limb deficiency at transradial or wrist level

- Unilateral limb deficiency

- Experience with myo-electric prosthesis

- No experience with more than one of the control types that will be examined

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Individuals that are younger than 18 years of age and/or have experience with both machine learning control and direct control will be excluded. Furthermore, individuals with an upper limb deficiency at another level than transradial or wrist level will not be included. In addition individuals with an amputation or congenital defects of both hands will be excluded.

Potential subjects for the able-bodied control group will be excluded if they have any musculoskeletal health issues or if they are younger than 18 years of age.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-08-2018
Aantal proefpersonen:	55
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6967
NTR-old	NTR7155
Ander register	METC : ABR 65604

Resultaten