PROSTHETIC: Prosthesis Training for Humans: Educational-games vs. Traditional-care and Innovative control vs. Classic-control

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON46075

Source
ToetsingOnline

Brief title
PROSTHETIC

Condition

- Other condition

Synonym
arm amputations, Upper limb deficiency at transradial or wrist level

Health condition

amputaties dan wel aangeboren afwijkingen aan de bovenste ledematen

Research involving

Human

Sponsors and support

Primary sponsor: Rehabilitation Medicine
Source(s) of monetary or material Support: Europese Unie;Revalidatiefonds Nederland;Universiteit Campus Friesland

Intervention

Keyword: Prosthetic control, Serious games, Training, Upper-limb Prosthetics

Outcome measures

Primary outcome

Outcome scores from a battery of clinical tests measuring prosthetic control capability and functional outcome. The primary outcome variable is the Partial Southampton Hand Assessment Procedure (P-SHAP) score (SHAP is a functional test often used in prosthetic research).

Secondary outcome

Secondary outcome variables are: Score in Clothespin Relocation Test, Score on Hysteresis test, Joint angles ranges and time to completion in tasks which resemble activities of daily living (ADL), and the System User Scale score.
Other measurements are: Accuracy scores and games scores during training sessions.

Study description

Background summary

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.

Study objective

The aim of this experiment is to collect preliminary data to guide future studies 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.

Study design

Explorative intervention study with pre-posttest design.

Intervention

Four groups will undergo a different training paradigm: Two groups will undergo standard clinical training for DC and ML, respectively. The other two groups will undergo training based on a serious game for DC and ML, respectively. A fifth group will establish a baseline and will not undergo any interventions.

Study burden and risks

All participants (except for the reference group) will start with a fitting session. During this session all participants will be fitted with a plaster custom-made socket. After the socket is fitted a 20 minute introductory session with the control mechanism will take place. In the next session the pre-test will be conducted. This session will last around 120 minutes of which 60 minutes consists of resting periods to not fatigue the muscles producing the control signals. In the seven sessions after the pre-test participants will partake in 7 training sessions of 45 minutes where they will use the muscles in the stump to practice myoelectric control. After these training sessions one last session containing the post-test will take place. This day is similar to the pre-test. The pre- and post-test will be held on days separate from any training session.

The risk associated with participating in this study are negligible, with muscle fatigue as the only risk. The burden is minimal since all sessions will take place under supervision within a month at a place chosen by the participant such as the participants home or at a clinic.

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

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

- Written informed consent
- Mastering the Dutch language

Exclusion criteria

Individuals that are younger than 18 years of age and/or have experience with both machine learning 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.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-11-2018
Enrollment:	55
Type:	Actual

Medical products/devices used

Generic name:	Handprosthesis
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	04-09-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	27-05-2019
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

No registrations found.

In other registers

Register	ID
CCMO	NL65604.042.18
Other	UMCG Research register: 201800308, NTR7155