Developing a new test for ability to control an arm prosthesis.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21071

Source
NTR

Health condition

This experiment will be executed with healthy subjects. Subjects with (history of) disorders of the arms and/or upper body will not be included. Subject who are experienced with the use of a prosthesis (simulator) will also be excluded.

Sponsors and support

Primary sponsor: A. Heerschop – a.heerschop@umcg.nl
Source(s) of monetary or material Support: UCF, Revalidatiefonds

Intervention

Outcome measures

Primary outcome

Primary outcome measure per test;

1. Table-top hand; The velocities of the opening and closing of a table-top prosthesis at three different speeds (slow, pleasant and fast). The angle of the regression line through the three velocities will be determined.

2. InterceptPlus; The velocities of the left/right movement of a virtual platform at three different speeds (slow, intermediate and fast). The angle of the regression line through the three velocities will be determined.

3. Cylinder grasp; The difference between the aperture of the hand and the diameter of three differently sized wooden cylinders. The angle of the regression line through the three differences will be determined.

4. BangBang; The difference between the aperture of the virtual gripper and the diameter of three differently sized virtual balls. The angle of the regression line through the three differences will be determined.

5. PEMG; The difference between the asked signal and the produced signal.

All of the above described measures will be ranked per test. These ranks will be analyzed. The ranking of the table-top hand will be considered the golden standard. This is the ranking on which the division between HP and LP is based.

Secondary outcome

Secondary outcome measures;

1. InterceptPlus;

a. Scores: related to the accuracy of following a light beam.

b. Error margins: difference between asked and delivered velocity.

c. Actual speed: actual speed of the platform.

Study description

Study objective

In the process of developing a serious game for testing patients' level of myocontrol a part of the test needs to be validated. This validation is the goal of the current study. The part of the test that needs to be validated focusses on the differentiation between high performers (HP) for myocontrol and low performers (LP) for myocontrol. In order to examine whether the test is able to detect this difference the test will be compared to four other tests testing comparable aspects of myocontrol. We expect to find no significant differences between the tests.

Study design

All subjects will be measured once. The study is interested in test-results without the effect of training or repetitions. The primary results are based on velocities which will be measured using either a goniometer in the prosthesis tasks or based on movements of the cursor on the screen in the game tasks.

Intervention

During this study all subject will undergo five tests. Two of these tests will be executed with the use of a myoelectric prosthesis simulator. The other three tests will be executed in a virtual environment, using serious games. Both the myoelectric prosthesis simulator and the serious games are controlled using surface EMG measured on the flexor and extensor of the wrist. The five tests are presented to the participants in a random order to prevent training effects.

Contacts

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Eligibility criteria

Inclusion criteria

The subjects included in this study are able bodied and right handed, with normal or corrected to normal vision. Both male and female subject will be included. All subjects included will be between 18 and 50 years of age.

Exclusion criteria

Subjects with (history of) pain or musculoskeletal impairments of the arms or upper body will not be included. The same accounts for subjects with prior experience in the use of myoelectric devices and subjects younger than 18 or older than 50.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	26-05-2015
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	21-05-2015
Application type:	First submission

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
NTR-new	NL5140
NTR-old	NTR5280
Other	: ECB 2014.02.28_1

Study results