Quantify the ability of the human hand to perform independent movements

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22010

Source
Nationaal Trial Register

Brief title
Symbionics

Health condition

Duchenne Muscular Dystrophy
Duchenne Spierdystrophie

Sponsors and support

Primary sponsor: University of Twente
Source(s) of monetary or material Support: STW

Intervention

Outcome measures

Primary outcome

The main study parameter is the amount of information in bits/sec people convey through their hands. This can change depending on the amount of stimuli, and their presentation rate (frequency). We are interested in measuring this.

Secondary outcome

The secondary study parameter is the workload every condition imposes on the subject (assessed via a questionnaire) and the difference between healthy people and people with DMD using our setup.

Study description

Background summary

Rationale: Current hand orthoses, do not take into consideration the limits of the human in terms of information transfer rate (ITR). Neither it is clear how many gestures can be distinguished in patients with DMD when using sEMG as a control input. A quantification of these limits can lead to a simplification of the design and control of such orthoses.
Objective: The main objectives of this study are to determine the rate people convey information through their hand and to assess the associated mental workload of the subjects through a questionnaire. The secondary objective is to determine to what extend sEMG can be used for controlling an active device. Moreover, as we already have pilot data from healthy subjects, we are also interested in the comparison between healthy people and people with Duchenne.
Study design: Explorative investigational study. Because of the physical limitations of people with Duchenne to respond fast by moving their fingers, we also want to measure EMG signals from the forearm in order to have the exact time of muscle activation. This is done for the sake of the comparison with healthy subjects.
Study population: A maximum of 6 patients with Duchenne Muscular Dystrophy (DMD), 18 - 28 years old.
Intervention (if applicable): The participants in this study will have to sit in front of an apparatus, which will provide them with visual stimuli (in the form of LEDs switching on and off). They will be responsible for clicking a mouse button, depending on the stimuli they receive. During the additional experiment the participants will be asked to make 7 different gestures which are presented on a screen.
Main study parameters/endpoints: The main study parameter is the amount of information in bits/sec people convey through their hands. This can change depending on the amount of stimuli, and their presentation rate (frequency). Also, the workload every condition imposes on the subject is assessed via a questionnaire.
Secondary study parameters/endpoints: The secondary study parameter is the capability of sEMG on the forearm of people with DMD to provide the necessary information to recognize different gestures. Additionally, the difference between healthy people and people with DMD will be evaluated.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The measurement protocol is not invasive, the measurements require some time investment of the subject. Participation in the investigation is not directly beneficial for the participants. A contribution is made to the future development of a new 'adaptive' hand orthosis.

Study objective

The main objective of this study is to determine the rate people convey information through their hand. The secondary objective is to assess the mental workload of the subjects through a questionnaire. Moreover, as we already have pilot data from healthy subjects, we are also interested in the comparison between healthy people and people with Duchenne.

Study design

All Outcomes will be measured at the same time point (Day of the measurement).

Intervention

None

Contacts

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Eligibility criteria

Inclusion criteria

-Age: 18-28 years

-Affected hand function

Exclusion criteria

-Above or below the age band allowed (18-28)

-Epileptic seizure history

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2016
Enrollment:	6
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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	NL6045
NTR-old	NTR6184
Other	METC Twente : METC NL59061.044.16

Study results