Testing of an instrument to assess arm-hand skilled performance in healthy children, children with cerebral palsy and adult stroke patients

Published: 20-03-2013
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Objective: Development of an instrument to objectively assess arm-hand skilled performance in daily life in typically developing children, children with CP and adults who suffered a stroke.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Central nervous system vascular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON40256

Source
ToetsingOnline

Brief title
Instrument assessing arm hand skilled performance

Condition

- Central nervous system vascular disorders

Synonym
cerebral palsy, stroke

Research involving
Human

Sponsors and support

Primary sponsor: Adelante Zorggroep
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cerebral palsy, skill performance, stroke, upper extremity

Outcome measures

Primary outcome

Main study parameters/endpoints: The 3 study parameters addressed in this study are: 1) the reproducibility of activities of daily living measured with *9-DOF sensors*; 2) the possibilities of identification of activities of daily living, based on pattern recognition techniques using the recorded signals; 3) quantification of quality of movement during the execution of activities of daily living.

Secondary outcome

not applicable

Study description

Background summary

Rationale: An accurate measurement of skilled arm-hand function in a home situation is important for both the patient and the rehabilitation team, since functioning in daily life is the ultimate rehabilitation goal. Currently no instrument exists to measure the quality of arm-hand use of the patient in the home situation.

Study objective

Objective: Development of an instrument to objectively assess arm-hand skilled performance in daily life in typically developing children, children with CP and adults who suffered a stroke.

Study design

Study design: non-randomised cross-sectional study.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: The risks of participating in this study can be considered as negligible. The activities which the children have to perform are all activities of daily living which pose no harm or risk to the participant. These activities are also performed by the participant during his/her daily life. The sensors which are used in this study (i.e. the SHIMMER sensors) are operated by a small, low-charge battery and pose no harm to the subject. The burden for participating in this study is minimal. The typically developing children and stroke patients participating in this study have to come to the rehabilitation centre once (with his/her parent) for 1 hour. The children with CP can undergo the measurement at the same place where they go to school and receive their regular therapy, so there is no need for travelling. During the measurement the burden is also minimal since the children only have to perform activities which they perform every day.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Part 1: typically developing healthy children
- Typically developing healthy child who is not suffering from any illness or disease that may affect arm-hand function.
- Age between 6 and 18 years
- No severe impaired communication as to comprehension
- Children and the parents/caregivers should comprehend and speak Dutch;Part 2: children with CP
- Child diagnosed with CP
- Age between 6 and 18 years
- Hagberg diagnosis: spastic hemiparesis or extreme asymmetric diplegia
- Hand function impairment Zancolli grade I with evident problems in thumb extension and supination, Zancolli grade IIA and IIB 15.
- No severe impaired communication as to comprehension
- Children and the parents/caregivers should comprehend and speak Dutch

Part 3: adults who suffered a stroke
- Adults diagnosed with supratentorial stroke
- Age * 50 years old
- Clinically diagnosed with a central paresis of the arm-hand
- Post-stroke time * 2 years
- No severe impaired communication as to comprehension
- Able to comprehend and speak Dutch

Exclusion criteria

Part 1: typically developing healthy children
- Presence of disease or illness affecting arm-hand function ;Part 2: children with CP
- Severe structural contractures of the muscles at the upper extremity (elbow extension deficit 20
degrees, supination deficit 45 degrees, deficit wrist dorsal flexion 30 degrees or more)
- Severe impairment of hand function (Zancolli III)
- Children who are hyper sensible and cannot bare touching the affected arm and hand;Part 3: adults who suffered a stroke
- A-functional arm-hand (Utrechtse Arm/Hand Test 21, score = 0)

- Severe neglect (Bell Test, Letter Cancellation Test: minimum omission score of 15% 16-18)
- Hemianopsia
- Severe spasticity (Modified Ashworth Scale total arm > 4)
- Severe additional neurological, orthopaedic or rheumatoid impairments which could interfere
with task performance
- Broca aphasia, Wernicke aphasia, global aphasia (determined by the Akense Afasie Test 19,
- Apraxia (Apraxiatest of van Heugten 20)

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-04-2013
Enrollment:	85
Type:	Actual

Ethics review

Approved WMO

Date:	20-03-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	05-05-2014
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL42965.068.12