Upper extremity strength in children and adolescents with and without unilateral Cerebral Palsy

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Encephalopathies
Study type	Observational non invasive

Summary

ID

NL-OMON41425

Source
ToetsingOnline

Brief title
Upper extremity strength in children

Condition

- Encephalopathies

Synonym
brain lesion, Cerebral Palsy

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: Stichting Vooruit voor kinderen met een handicap & Stichting Innovatie Revant

Intervention

Keyword: children, CP, strength, upper extremity

Outcome measures

Primary outcome

Primary outcome measures: the most important psychometric property to investigate in terms of muscle strength evaluation is reproducibility. Reproducibility in this study will be assessed by looking at the following factors: Intraclass Correlation Coefficient (ICC), Limits Of Agreement (LOA), Standard Error of Measurement (SEM) en de Smallest Detectable Difference (SDD). Reference values for upper extremity muscle strength in children and adolescents will be determined by using the Generalized Additive Models for Location, Scale, and Shape (GAMLSS) method.

Secondary outcome

not applicable

Study description

Background summary

Rationale: Sixty percent of the children and adolescents with Cerebral Palsy (CP) experiences problems with their arm and hand function in daily pursuits. There is increasing evidence that strength in the affected arm in children with a unilateral CP is a good predictor for the use of this arm in bimanual performance. There is also evidence that upper extremity muscle strength in children with CP, in the affected arm as well as in the non-affected arm, is less compared to typically developing peers. To be able to evaluate upper extremity muscle strength in children with CP properly, there is a need for valid and reliable measurement instruments. A systematic review on psychometric properties of upper extremity strength measurement instruments showed that there only a few studies published on this topic and that the methodological

quality of these studies is low.

Study objective

The aim of the present study is to investigate the reproducibility of upper extremity strength measurements in children with CP. The following strength measurement instruments will be studied: Hand Held Dynamometry (HHD), pinch- and grip strength measurements using the E-link system and functional strength measurements. To study how upper extremity muscle force in children with CP is related to the upper extremity muscle force of typically developing peers, these measurements will also be administerd in normal age-matched children.

Study design

Study design: a 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 risk of particpating in this study can be considered very low. The movements these children have to make are not different from the movement during activities of daily living. HHD and the E-link system are often used in clinical practice. The functional strength measurements are similar to activities of daily living , i.e. carrying a crate (bimanual) and holding a jug (unimanual). The movements pose no harm or risk to the patient. The burden of participating in this study is alo low. Children have to invest maximal 3 hours. The burden of the typically developing peers who are assessed to gather reference data is only 1 hour. The children with CP can undergo the measurements at the same place where they go to school and receive their regular therapy, so there is no need for travelling. The measurements of the typically developing children will be organised in a similar manner at their school or club.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Children with CP:
* child diagnosed with CP, unilateral or bilateral with a clear difference between the left and right side
* age between 7 and 18 years
* GMFCS level I-III
* MACS level I-III
* enough intellectual ability to understand easy tasks
* children and their parents/caregivers should comprehend and speak Dutch;Typically developing children:
* attending regular primary or secondary school
* age between 7 - 18 years
* children and their parents/caregivers should comprehend and speak Dutch

Exclusion criteria

Children withCP:
* surgical intervention < 6 months
* Botulinum Toxin A treatment in the upper extremity in the past 6 months
* Contractures in the upper extremity disturbing functional use;Typical developing children:
* Muscle disease

* Injuries, fractures or casting of the upper extremity in the past 6 months

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-09-2014
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	23-05-2014
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	03-02-2016
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
ClinicalTrials.gov	NCT02146989
CCMO	NL45430.068.13