TOAST-CP: Task-Oriented Arm Strength Training in children with Cerebral Palsy

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The goal of the study is to enhance the participation in daily life of children with CP, by increasing their independent use of the upper limb performing daily life activities. By training the task oriented strength in daily life activities...

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

Summary

ID

NL-OMON40662

Source
ToetsingOnline

Brief title
Task-Oriented Arm Strength Training in children with Cerebral Palsy

Condition

- Encephalopathies

Synonym
brain lesion, cerebral palsy

Research involving
Human

Sponsors and support

Primary sponsor: Adelante Zorggroep
Source(s) of monetary or material Support: Johanna Kinderfonds;NutsOhra;Revalidatiefonds;Stichting Vooruit

Intervention

Keyword: Cerebral Palsy, Children, Task-oriented strength training, Upper limb

Outcome measures

Primary outcome

Activity Level

At the activity level, measures of hand skills, bimanual performance and manual ability will be used.

Primary outcome measure:

The Assisting Hand Assessment (AHA) measures the typical performance of a child*s assisting hand in a range of bimanual activities. The AHA measures ability and performance of use of the affected hand in bimanual play by standardized video observation.

Secondary outcome

Activity Level

At the activity level, measures of hand skills, bimanual performance and manual ability will be used.

Primary outcome measure:

The Assisting Hand Assessment (AHA) measures the typical performance of a child*s assisting hand in a range of bimanual activities. The AHA measures ability and performance of use of the affected hand in bimanual play by

standardized video observation.

Secondary outcome measures:

Activity Level

1. The Observation and Scoring of Arm hand Skills (OSAS) is a video-based observation system to observe the spontaneous use of the affected limb in standardized bimanual fine and gross motor tasks (threading beads task, construction tasks small and large, making a sandwich tasks and stacking cylinder tasks).

2. The ABILHAND-Kids is a 21-item questionnaire based on existing scales and expert advice. The ABILHAND-kids is a functional scale specifically developed to measure manual ability in children with CP (up to 12 years).
3. The Jebsen Taylor test will be used to score the velocity of the use of the affected hand in functional standardized tasks.

Participation Level

1. The domain frequency of use of the Children's Assessment of Participation and Enjoyment (CAPE) and Preferences for Activities for Children (PAC) will be used to document this outcome. The CAPE/PAC has been developed to determine the outcome on participation once per three months.

2. Enjoyment of the child during the training will be assessed using the Youth Rating Scale of the Behavioral and Emotional Rating Scale Second Edition (BERS-2).

Body function/Body structure

At the body function/ structure level (ICF-CY), measurement of muscle strength, spasticity and active and passive range of movement will be performed.

1. Measurement of strength will include both dynamic and isometric components of strength and the next tests will be performed:

a. Grip and pinch strength will be measured using the E-link from Biometrics (isometric strength) (http://www.biometricsltd.com/REHAB.htm

b. The isometric strength of wrist and elbow muscles will be measured using Hand Held Dynamometry (HHD). The Microfet-2 will be used, using the make method. (http://www.biometrics.nl/produkten.php?ms_id=196&Instrumenten/Spierkracht/MicroFET_2.)

c. Task-oriented strength will be measured during performance of specific tasks related to their three defined goals: two examples are the crate task (bimanual lifting) and the measuring cup task (unimanual lifting). Strength will be expressed as number of Kg lifted and kept in one standardized

described position for five seconds.

2. Goniometry will be used to measure an angle of catch (high velocity stretch), presenting a measure for spasticity.45 Goniometry will also be used to measure active and passive Range of Motion (ROM) of the wrist, elbow and shoulder. A Lafayette Gollehon extendable goniometer (model 01335) will be used to measure ROM. (http://www.lafayetteevaluation.com/product_detail.asp). A standardized protocol with standardized positions will be used. The protocol has been used in the Botulinum Toxin Bimanual Skills study (BoBiVa).

Study description

Background summary

Cerebral palsy (CP) is the most common cause of movement disability in childhood. The incidence is 1.5-2.5 per 1000 live born children and has remained stable over recent years. Children with CP experience limitations in motor activities and participation in the community, predominantly caused by impairments in muscle function. Aside from abnormal posturing due to spasticity, muscle weakness can significantly contribute to impaired muscle function and there is increasing evidence that muscle weakness significantly impairs upper limb motor function and ability to perform manual tasks in children with CP. Strength training is expected to reduce limitations in activities of children with CP.
When strength training is applied, the guidelines of the National Strength and Conditioning Association (NSCA) can be used.NSCA recommend training after seven years of age. Strength training should involve a progressive intensity, thereby stimulating strength gains that are greater than those associated with normal growth and development. This is known as Progressive Resistance Exercise (PRE), with a duration of at least 12 weeks. This method of strength training has previously demonstrated efficacy in children with CP without injury or problems with compliance during a 12-week program.
As shown, strength training focused on specific muscle groups (single joint training) will not improve everyday activities. Furthermore, it is shown that in the first 6-18 weeks of strength training little adaptation of muscle tissue will occur, but mainly specific neural adaptation will take place during this

training period. Based on the strength training guideline from the NSCA , it is concluded that motor learning theory should be incorporated into strength-training practice. Based on both the guidelines for strength training and the fact that neural adaption will occur mainly in the first 8-12 weeks of training, we developed Task Oriented Arm Strength Training in children with CP (TOAST-CP). In TOAST-CP we will perform the strength training with loaded objects from daily life such as a bucket, a measuring cup, a belt and a crate, to ensure the specificity of the neural adaptation for the trained activities.
In TOAST-CP the PRE training method will be used because it appeared to be a safe training method for children with CP. No study has investigated the effects of TOAST-CP on the performance of the activities of daily life and strength. In contrast, usual care with specific manual skill learning program, without any embedded strength training will be performed. The effect of TOAST-CP on the performance of daily activities will be compared with the effect of manual skill learning on the performance of daily activities.

Study objective

The goal of the study is to enhance the participation in daily life of children with CP, by increasing their independent use of the upper limb performing daily life activities. By training the task oriented strength in daily life activities following TOAST-CP the independent use of the upper limb in bimanual activities of daily life will increase.

Study design

A multi Centre Randomised Clinical Trial (RCT)

Intervention

After inclusion the TOAST-CP treatment will start based on the three selected goals and an analysis of the task performance will be made of each of these three goals. The results of the task analysis will serve as basis for the individualized treatment of participants allocated to the TOAST-CP group. All TOAST-CP participants will receive 30-minute contact sessions three times a week over a 16 week period. Based on earlier research, it was established that three goals can be trained in 30 minutes.
The control group will receive usual care, without any strength intervention, 1-3 times a week over a period of 16 weeks. Both groups will receive individually based interventions and these interventions can be easily planned into a regular rehabilitation schedule.

Experimental group
Task-oriented strength training protocol - TOAST-CP program-

Participants assigned to the experimental group will perform an individualized TOAST-CP program. The exercises in TOAST-CP will be based on 1) the three defined goals, 2) the outcome of the analysis of the task performance and 3) a specific strength analysis will be performed based on the chosen exercises.
The Repetition Maximum (RM) model will be used to determine the load. All exercises based on the task analysis will be loaded with weight to determine the 10-15 RM. According to the nature of task-oriented strength exercises, a set of muscles required to perform the functional task will be trained and targeted. Examples of these tasks are lifting a bucket, carrying a tray, making a sandwich, fastening a belt and lifting a mug.
The training method is Progressive Resistance Exercise (PRE). This method of strength training has previously demonstrated efficacy in children with CP without injury or problems with compliance during a 12-week program. Using the NSCA guidelines, a training load of 10-15 RM, three sets with a 90-second rest period will be used.
The PRE training lasts 16 weeks. The first two weeks consist of unloaded task-oriented exercises, with the focus on the quality of the performance of the task. To determine the load of 10-15 RM, measurement will take place at conclusion of the second week. In the third and fourth week the load of the task-oriented exercises will be increased up to the level of their individual 10-15 RM. At the start of week five, the 10-15 RM training will be started and at conclusion of each week the load will be re-measured and adapted.
From week five to week 16 (12 weeks) the load will be increased 10-20% per week, if a block of three sets of 10-15 RM is possible.

Control group
Usual Care (Manual Skill Learning)

Participants assigned to the control group will receive usual care (manual skill learning).
The exercises in the control group will be based on the three defined goals. Based on the three main goals individualized manual skill learning will be performed, without any strength training.

Study burden and risks

Both measurement sessions and training sessions are wthout any additional risks, compared to daily life activities, usal care and clinical investigation. Measurement and training of strength are well known professional activities for rehabilitation therapists and frequently used in usual care. The type of strength training -Progressive Resistive Exercise training (PRE)- is the most frequently used type of training, save for children and advised by the National Strength and Conditioning Association (NSCA). The use of strength training in upper extremity is innovative but based on PRE.
Training and measurement schedule is completely adapted to the rehabilitation

model of 30 minutes of training, 2-3 times per week, in balance with special school schedules.
The measurements sessions will be adpated to this time schedule and will be fitting in the daily schedule of the rehabilitation and school, without additive time or in competition with the lessons on school.

Contacts

Public
Adelante Zorggroep

Zandbergseweg 111
Hoensbroek 6432 CC
NL
Scientific
Adelante Zorggroep

Zandbergseweg 111
Hoensbroek 6432 CC
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Age 8-18 years
* Spastic Cerebral Palsy (according to the Surveillance of Cerebral Palsy in Europe (SCPE)
* Gross Motor Function Classification System (GMFCS) I-IV

* Manual Ability Classification System (MACS) I-III
* Hand function impairment Zancolli grade I- IIB
* Children have to be able to comprehend tasks and perform the measurements and training, judged by the rehabilitation physician of the project team. The clinical data of the children regarding cognitive deficits and learning difficulties are available for this study.
* Able to communicate in Dutch or English.
* * Realistic problems performing manual activities.
* Reduced upper limb strength.
* Strength difference between the left and right arm of at least 20%.
* Children and their parents indicate the necessity for improvement of the children*s manual abilities

Exclusion criteria

* Severe impairment of hand function: no active hand function (Zancolli III)
* Upper limb hand surgery within the last six months
* Botulinum toxin-A injection of the upper limb within the last three months
* Have undertaken an upper limb specific strength training program within the last three months
Botulinum Toxin-A or Surgery is necessary during the trial period.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	11-09-2015
Enrollment:	50

Type:	Actual

Ethics review

Approved WMO Date:	13-10-2014
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

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	NL49818.015.14
Other	TC= 4668

Study results

Results posted: 03-04-2018

First publication
01-01-1900