Strength training in bimanual tasks for children with cerebral palsy

No registrations found.

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

Summary

ID

NL-OMON22757

Source
NTR

Brief title
TOAST-CP

Health condition

TOAST-CP
bimanual activities of daily life
upper limb strength.
manual skill learning

Sponsors and support

Primary sponsor: Adelante zorggroep
Source(s) of monetary or material Support: NutsOhra
Johanna Kinderfonds
Revalidatie Fonds
Stichting Vooruit

Intervention

Outcome measures

Primary outcome

Measurements across all domains of the ICF-CY are used. All measures are administered and scored by raters blinded for group assignment.

Primary outcome measures will be as follows:

- Activity Level

- At the activity level, measures of hand skills, bimanual performance and manual ability will be used. Based on the aim of the study - to improve the ability of the use of both hands - the primary outcome measure will be the Assisting Hand Assessment (AHA).

Furthermore, the children with CP in an earlier study (Botulinum Bimanual Skills Study) prioritized problems in performing the manual tasks and mention the ability to use both hands and amount of use of both hands, the speed of performance and quality of performance. Based on these issues the next tests are selected:

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. It is validated for children with unilateral CP, aged 1.5 to 12 years.The interrater reliability of the sum scores is excellent (0.97 (0.91-0.99)

Secondary outcome

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). These tasks have shown a very good intrarater reliability of 87% -91% agreement and interrater reliability of 72% -84% agreement in children with unilateral CP (prepared to submit). The OSAS will be scored by one blinded assessor. Duration of the use of the affected hand in these bimanual skills will be scored.

2. The ABILHAND-Kids is a 21-item questionnaire based on existing scales and expert advice 40. The ABILHAND-kids is a functional scale specifically developed to measure manual ability in children with CP (up to 12 years). A high reliability (R = 0.94), and a good reproducibility over time (R = 0.91) have been shown. The original ABILHAND will be used for the adolescents (12-18 years), which has shown a good reliability and reproducibility.

3. The Jebsen Taylor test will be used to score the velocity of the use of the affected hand in functional standardized tasks. For the dominant hand, the test-retest reliability in patients with stable hand disorders is high (R=0.89 to 0.99), except for the writing subtest (R=0.67). With the non-dominant hand the simulated feeding subtest is the least reproducible (r=0.60).

The test seems to be sensitive enough to detect changes in hand function in patients with different impairments.

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. This aims to evaluate the effect of training in a child’s typical environment (in the family, with friends, at home, at school, in sports and hobbies). The CAPE / PAC has a moderate to good test retest reliability (0.68-086) and moderate to good interrater reliability 0.47-0.99.

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).

Test-retest reliability coefficient of the Parent Rating Scale Composite Strength Index (r = .87) with subscales ranges from 0.82 to 0.92. The Youth Rating Scale Composite Strength Index (r = 0.91) with subscales ranging from 0.84 to 0.91. BERS-2 can be used form 5-18 years of age. For younger children the Smiley Face five rating satisfaction scale will be used.

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). In a pilot study (32 adolescents with unilateral CP) we found high test-retest reliability for fist and pinch grip measurement (ICC 0.99) (not yet published).

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.44 In a recent pilot study (32 adolescents with unilateral CP) good test retest reliability has been demonstrated for testing the upper limb muscles in children with unilateral CP (ICC 0.73- 0.96). (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. The crate and measuring cup tasks have demonstrated good test retest reliability in a recently completed pilot study (32 adolescents with unilateral CP) (ICC crate task 0.94, measuring cup task 0.96).

2. Goniometry will be used to measure an angle of catch (high velocity stretch), presenting a measure for spasticity. 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

Rationale: Based on the latest research and clinical insights, we recently developed a promising and innovative approach to increase manual performance of daily activities in children with spastic Cerebral Palsy (CP), namely Task-Oriented Arm Strength Training (TOAST-CP).

Objective: To compare the effectiveness of TOAST-CP with manual skill learning in improving the performance of manual daily activities in children with spastic CP.

Methods/Design: This multicenter randomized controlled trial will investigate the effectiveness of TOAST-CP in children with spastic CP, involving 50 participants aged 8-18 years. Participants will be recruited from rehabilitation centers and outpatient physiotherapy clinics. Eligible participants will be randomly allocated to either TOAST-CP or usual care related to manual skill learning.

Intervention: The participants of the intervention group will perform a TOAST-CP program, based on individual goals and guided by an algorithm. The control group will receive usual care related to manual skill learning program. The contrast between both groups is based on the training according to strength training guidelines in a task oriented concept versus practicing manual skills without any strength training involved. TOAST-CP consists of an individual-based 30 minute session, three times a week over a 16 week period. Control group will receive usual care without any strength related training.

Outcome: Outcome will be measured at baseline at eight, 16 (end of training), three and six months after training.

Primary aim of the training is to improve the level of performance of both hands in manual daily activities and primary outcome will be measured at the level of activity. As a primary outcome the Assisting Hand Assessment (AHA) will be used. The AHA measures the performance and capacity of use of the affected hand in bimanual play in standardized way by video. Other secondary outcome measures, at the level of activity, are the Observation and Scoring of Arm Hand Skills (OSAS) (performance and amount of use of both hands), the ABILHAND (-Kids) (manual ability questionnaire) and the Jebsen Taylor test (speed of hand use). At the activity and participation level (ICF-CY), the most important goals for the child and his/her parents will be scored by Goal Attainment Scaling (GAS). The Children's Assessment of Participation and Enjoyment (CAPE) will be used to document change in how children and youth participate in the community. At the body function/body structure level measurements of passive and active range of movement and spasticity (Spasticity Test (SPAT)) will be used. Task-oriented strength, muscle related strength and isometric grip task will be measured.

Discussion: This is the first randomized controlled trial comparing TOAST-CP with usual care related to manual skill learning. Using high-quality methodology, this trial will add evidence to the gap in knowledge about the effect of strength training in children with CP.

6-10 Rehabilitation center in the Netherlands will participate in this multicenter trial.

Study objective

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.
Studies in the last decade have shown that muscle weakness, not spasticity, is the greatest limiting factor of motor function in children with CP. This has shifted the focus from spasticity management towards strength training in children with CP. Consequently, strength training is expected to reduce limitations in activities of children with CP.
Based on the latest research and clinical insights, we recently developed a promising and innovative approach to increase manual performance of daily activities in children with spastic Cerebral Palsy (CP), namely Task-Oriented Arm Strength Training (TOAST-CP).
Objective: To compare the effectiveness of TOAST-CP with manual skill learning in improving the performance of manual daily activities in children with spastic CP.
Both programs will improve everyday activities and the use of both hands, but the TOAST-CP program will possibly lead to a faster improvement in the performance of everyday activities. This effect can decrease the period of upper limb treatment. Furthermore, the increased strength after the TOAST-CP will ensure that everyday activities will be more easily executed compared to solely manual skill learning, increasing the long lasting independent use of both hands in everyday activities.

Study design

Participants are assessed by blinded testers at baseline, after eight weeks of training, after completion of the intervention period at 16 weeks, and at three and six months after the treatment, to assess the long term outcome of the intervention. Tests will be performed at the same location the child receives the training.

Each measurement session will take 90 minutes. These measurement sessions will be performed in several shorter periods of measurement during one week, in order to fit easily into a regular program for the children and their parents. The tests will be performed in random order to prevent fatigue. The tests are easy to perform and fun to execute for the children.

Intervention

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 8-12 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 program8. Using the NSCA guidelines, a training load of 8-12 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 8-12 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 8-12 RM. At the start of week five, the 8-12 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 8-12 RM is possible.

A detailed program has been developed by the investigators. In this program examples of exercises, based on the most frequently chosen goals are described. This program will guide the therapists. The principles of training will be taught beforehand in a one day program.

This method has been shown to be very useful for therapists to perform strength training.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.

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Eligibility criteria

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

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2015
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-07-2014
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	NL4533
NTR-old	NTR4668
Other	NL4981801514 CCMO : TOAST 2011/0094-1716 Nutsohra

Study results