

Strength training in bimanual tasks for children with cerebral palsy

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22757

Bron

Nationaal Trial Register

Verkorte titel

TOAST-CP

Aandoening

TOAST-CP

bimanual activities of daily life

upper limb strength.

manual skill learning

Ondersteuning

Primaire sponsor: Adelante zorggroep

Overige ondersteuning: NutsOhra

Johanna Kinderfonds

Revalidatie Fonds

Stichting Vooruit

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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))

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland
Status: Werving nog niet gestart
(Verwachte) startdatum: 01-01-2015
Aantal proefpersonen: 50
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 10-07-2014
Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4533
NTR-old	NTR4668
Ander register	NL4981801514 CCMO : TOAST 2011/0094-1716 Nutsohra

Resultaten