Effect of functional power training on the walking ability of children with spastic cerebral palsy in the age of 4 to 10 years

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The purpose of this study is to examine whether walking ability and plantar flexor strength of young children with CP who follow functional power training improve more compared to usual care.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Structural brain disorders
Study type	Interventional

Summary

ID

NL-OMON40459

Source
ToetsingOnline

Brief title
MegaPower training

Condition

- Structural brain disorders

Synonym
'Spastic Cerebral Palsy', 'spastic child'

Research involving
Human

Sponsors and support

Primary sponsor: Amsterdam Rehabilitation Research Center | Reade
Source(s) of monetary or material Support: Reade;centrum voor revalidatie en reumatologie

Intervention

Keyword: Cerebral Palsy, Muscle strength, Power training, Walking ability

Outcome measures

Primary outcome

Primary study parameters;

The objective primary outcome to measure the effect of the MegaPower training is the Muscle Power Sprint Test (MPST). The Goal Attainment Scaling (GAS) is the subjective, reported by the parents, primary outcome.

The MPST is a 6 times 15 meter sprint test. Between the 6 sprints is a 10 sec break in which the child can turn and be ready for the next sprint. The time used for each sprint is measured with 0.01 second precision. Together with body height and weight power will be calculated and expressed in Watts. The MPST measures the anaerobic capacity of the child expressed in mean power and peak power. The reliability of the test is good (ICC=0.97).

With GAS the extent of reaching the treatment goal will be measured. GAS is a sensitive, individual, evaluative measurement which describes the change of individuals or groups after treatment (ICC = 0.86).

Secondary outcome

Secondary study parameters

The secondary study parameters on the activity and participation level of the ICF-CY are the 1 Minute Walk Test (1MWT), 10 meter Shuttle Run Test, the Functional Mobility Scale (FMS), the Mobility questionnaire (MoVra28), Gross Motor Function Measure Dimension D and E (GMFM D&E), and the comfortable walking speed determined during the gait analysis.

The 1 MWT measures the distance walked in 1 minute. The children are asked to walk as fast as possible without running. The reliability is good (ICC=0.89 (4-5 year old children with CP), en ICC=0.94 (6-10 year old with CP). Aerobic capacity will be measured with the 10 meter Shuttle Run Test made for children with CP GMFCS level I and II (Reliability: ICC = 0.97 tot 0.99). The FMS is a questionnaire to classify the functional mobility in children with CP in the age of 4 till 18 years old (Reliability: Kappa 0.86-0.92). The MoVra28 is a questionnaire for children from 2-13 years old to determine the extent of problems the child has with his ambulation. The test contains 28 questions about daily activities and has a good reliability (ICC 0.87-0.99). Gross motor function such as standing on one leg, walking and turning, running and jumping are measured in a standardized way with the GMFM D&E (ICC 0.87-0.99).

The secondary outcome measures in terms of body function and structures are isometric muscle strength of the calf muscles, quadriceps and abductors and dynamic muscle strength of the calf muscles. The isometric muscle strength is measured with a hand-held dynamometer (microFET Hand-held Dynamometer, Biometrics BV, Almere) (ICC 0.79 - 0.96). The dynamic muscle strength will be measured with the unilateral heel-rise test (ICC 0.86 - 0.98).

During gait analysis the peak knee angle in Mid Stance and Terminal Stance will be determined by observing the two and three dimensional video recordings (ICC 0.85-0.96). The Maximum Voluntary Contraction will be assessed with the electromyography (EMG) of the calf muscles during the isometric muscle strength measurement. Using also EMG during the gait analysis, the muscle activity (%MVC) during walking can be determined.

Body height, body mass, probability of motor selective movements in hip, knee and ankle, presence of catch in the lower extremities and the muscle length of the m.gastrocnemius, m.soleus and hamstrings will be measured.

Study description

Background summary

Introduction
Children with cerebral palsy (CP) is the largest group treated in pediatric rehabilitation. Prevalence rates of CP are about 2 per 1000 births in Europe of which 82% has a spastic CP. Motor impairment in CP is multi-factorial and includes problems such as spasticity, coordination problems, loss of selective motor control and muscle weakness. Children with CP have problems with their walking ability in terms of walking speed, duration and they fall more often than typically developing children. Therefore, they experience more problems in daily live and during playing. Parents and/or children often ask for help for improving the walking ability in the clinical practice already at an early age. Children with CP develop their walking ability and walking pattern from the moment they start with walking till about 8 years old. It is important to guide the children in improving their walking ability at this early stage.
In clinical practice we often see that the push off is not efficient, which results in problems in clearance of the foot during walking and causes the many falling incidents. Also the stride length is short because of the diminished push off in children with CP. In typically developed walking 50-70% of the push off is delivered by the strength of the calf muscles. Children with CP have muscle weakness especially in the more distal muscles of the lower limbs, such as the calf muscles.
We, therefore, developed a functional power training program, called MegaPower training, in which they have to use maximal effort of the calf muscles during functional and known movements such as walking, running and climbing stairs. The velocity when performing the exercises is the velocity that is common for the activities they encounter in daily live. The difference between power training and the more traditional strength training programs are the higher velocity and the functional multi-joint character of the exercises. The children are guided carefully during the exercise by the trainer. A story about super heroes keeps the children motivated to give their best effort during the training.
In Reade the MegaPower training is already implemented in clinical practice. From 2011-2012, Reade got financial support from health insurance Agis to develop and implement the MegaPower training for children from 4-10 years with spastic CP. Pilot results from the children trained so far at Reade seem very

positive. Before we can implement the MegaPower training at more locations, it is important to know the real (i.e. evidence-based) effect of the MegaPower training on the walking ability for children from 4-10 years with spastic CP.

Study objective

The purpose of this study is to examine whether walking ability and plantar flexor strength of young children with CP who follow functional power training improve more compared to usual care.

Study design

Procedure
This research protocol has a *double-baseline* research design. The children that participate are their own controls by measuring their walking ability in the 14 weeks before the training intervention starts, which is the period of usual care. Thereafter, they follow the functional power training to be tested in this study. Fourteen weeks after the end of the training, a follow-up test is scheduled to assess if the potential improvement is remained.
The 'double baseline' design is chosen instead of a randomized control trial (RCT) to increase the feasibility of the study and to measure the change within the individual children in a better way. Parents often prefer the participate in the intervention group above a control group in a RCT, which makes it hard for them to participate in a study if they are not certain to get the intervention. The number of children that are to be included will be more in a RCT than in a 'double baseline' design, which makes the double-baseline design more feasible. Graham et al (2012) recently described the disadvantages of a RCT e.g. the strict inclusion and exclusion criteria of a RCT design make it difficult for therapists and clinical practitioners to generalize the outcome of the RCT to their patients in clinical practice. Graham et al (2012) described the 'double baseline' design as proposed in the present study as an alternative method in which less patients have to be measured.

Intervention

The functional power training (MegaPower training) has three elements: 1. warming-up (10 min), 2. power training (35 min), 3. play (15 min).
Key elements of the power training are; a.) functional loaded, muti-joint exercises like running and walking with focus on the push-off, b) the velocity of the movement during the exercises is the same velocity as used in daily/playing activities, c) 25 till 30 sec maximal effort will be asked of the children, thereafter they have a resting period of 30 till 50 sec., with 6 till 10 repetitions each exercise, d) Load will increase when possible during the weeks of the training period, e) training volume exists of load, velocity and number of repetitions, f) to motivate the children and control the movements

during the exercises they all have a personal coach.

Study burden and risks

The only risk of participation in this MegaPower will be muscle soreness. The frequency and severity of muscle soreness will be monitored during the training.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Children with diagnosis of predominantly spastic type of Cerebral Palsy, aged 4-10 years, being ambulant without assistive devices (GMFCS level I and II).
Parents and/or the children want to improve the walking ability of the child.

The children are able to follow instructions to perform the exercises and tests.

Exclusion criteria

Treatment with botulinum toxin A in lower limb or serial casting of lower limb less than 6 months before the MegaPower training starts.
Treatment of selective dorsal rhizotomie less than 12 months before the MegaPower training starts.
Walking is not (yet) the preferred way to move around.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	19-11-2013
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	16-10-2013
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	04-12-2014
Application type:	Amendment

Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)
Approved WMO Date:	23-12-2014
Application type:	Amendment
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 21727
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL46189.048.13
OMON	NL-OMON21727