

Effect of a lower limb strength training program on physical functioning in children with cerebral palsy

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The purpose of this study is to determine the effects of a strength training program on physical functioning in children with CP.

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|------------------------------|--|
| Ethical review | Approved WMO |
| Status | Pending |
| Health condition type | Movement disorders (incl parkinsonism) |
| Study type | Interventional |

Summary

ID

NL-OMON31736

Source

ToetsingOnline

Brief title

Popeye-onderzoek

Condition

- Movement disorders (incl parkinsonism)

Synonym

spastic children, Spastic diplegia and hemiplegia

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: JohannaKinderfonds;Kinderfonds
Adriaanstichting;Phelpsstichting

Intervention

Keyword: cerebral palsy, children, physical functioning, strength training

Outcome measures

Primary outcome

Physical functioning is evaluated using the Gross Motor Function Measure, functional tests, walking ability, and a mobility questionnaire.

Secondary outcome

Muscle strength of the lower limbs is tested using hand held dynamometry and functional tests, and spasticity is determined with the spasticity test, based on the modified Tardieu scale.

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 living born children and remained stable over recent years. Children with CP experience limitations in activities and participation, which is mainly caused by impairments in muscle function. Not only spasticity contributes to impaired muscle function, but also muscle weakness can be regarded as a serious denominator of impaired muscle function. Strength training is therefore expected to reduce limitations in activities of children with CP who will encounter life long disability. However, systematic strength training has received little attention until now.

Study objective

The purpose of this study is to determine the effects of a strength training program on physical functioning in children with CP.

Study design

Participants will be randomly allocated to a school-based strength training program, with a frequency of three times a week and a duration of 12 weeks, or to a control group following their usual therapy program. Measurements will be

performed before the training program, and after 6 and 12 weeks of training. In addition, a follow-up measurement at 6 weeks after the end of the program will be performed to investigate long-term effects.

Intervention

The group training program will be based on an existing individual training program for children with CP and will be further developed according to current guidelines for strength training in children. Strength training exercises and training of functional activities will be combined.

Study burden and risks

It is hypothesized that a structured and regular strength training program increases muscle strength, which is expected to improve physical functioning in children with CP, without any adverse effect on muscle spasticity. Muscle soreness is likely to occur, but is also expected to be temporarily. Joint complaints are the most likely physical complaints. Risks are comparable to usual sport and therapy situations.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)

Adolescents (16-17 years)

Children (2-11 years)

Inclusion criteria

Children with spastic hemiplegia and diplegia, with GMFCS levels I, II and III (ambulant with and without aids, Palissano 1997) and aged from 6 to 13 years, will participate.

Exclusion criteria

Children will be excluded if they have instable seizures, if they received (surgical) treatment for spasticity or surgical procedures up to 4 months prior to the study (or planned in the study period), if there is an expected change in medication during the study period, or if they suffer of other diseases that interfere with physical activity (judged by the physician).

Study design

Design

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

Primary purpose: Treatment

Recruitment

| | |
|---------------------------|-------------|
| NL | |
| Recruitment status: | Pending |
| Start date (anticipated): | 20-08-2007 |
| Enrollment: | 50 |
| Type: | Anticipated |

Ethics review

Approved WMO

Application type:

First submission

Review commission:

METC Amsterdam UMC

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 | NL16552.029.07 |