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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21600

Source
NTR

Brief title
the Popeye study

Health condition

cerebral palsy
children
muscle strength
progressive resistance exercise (PRE)
strength training
physical therapy

Sponsors and support

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Source(s) of monetary or material Support: The Johanna KinderFonds
The Adriaanstichting
The Phelps Stichting

Intervention

Outcome measures

Primary outcome

Physical functioning is measured as gross motor function and walking ability

Gross motor function:

- Gross Motor Function Measure (GMFM)

- Functional muscle strength tests (30 second Lateral Step Up test; 30 second Sit to Stand test)

Walking ability

- The 10-meter walk test

- The 1-minute walk test

- The timed stair test

Secondary outcome

Lower limb muscle strength

- 6RM test

- Isometric muscle strength tests of 5 lower limb muscles using hand-held dynamometry(knee flexors and extensors, hip flexors and abductors, ankle plantar flexors)

- Lower limb sprint capacity test (Wingate test)

Mobility

- The mobility questionnaire (MobQues)

Sport activities

- The Children's Assessment of Participation and Enjoyment (CAPE)

Advers events:

- Spasticity

- Range of motion

Study description

Background summary

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

Study objective

We hypothesize that children who will follow this structured functional PRE strength training program will increase in muscle strength, which accordingly will lead to functional improvement in physical functioning, but with no negative effect increasing spasticity or decreasing range of motion, compared to children receiving usual care.

Study design

To evaluate the effectiveness of the training, all children are evaluated before, during, directly after, and 6 weeks after the intervention period.

Intervention

Using stratified randomization, each child is assigned to an intervention group (strength training) or a control group (usual care).

The strength training is given in groups of 4-5 children, 3 times a week, for a period of 12 weeks. Each training session focusses on four exercises out of a 5-exercise circuit. The exercise are maily functional, aiming at a maximal carry-over into everyday activities. The

training load is gradually increased based on the child’s maximum level of strength, as determined by the 8 Repetition Maximum (8RM).

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 6 and 13 years

2. Able to accept and follow verbal instructions

3. Ability to walk independently indoors, with or without walking aids (Gross Motor Function Classification System [GMFCS] levels I – III)

4. Able to participate in a group training program

5. Attending a school for physically disabled children

Exclusion criteria

1. Instable seizures

2. Received treatment for spasticity or surgical procedures up to 3 months (for botulinum

toxin type A injections) to 6 months (for surgery) prior to the study (or planned in the study period)

3. Expect any change in medication during the study period

4. Suffer from other diseases that interfered with physical activity.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2007
Enrollment:	50
Type:	Actual

Ethics review

Positive opinion

Date:	13-08-2008
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	NL1343
NTR-old	NTR1403
Other	: WC05-043
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A