LEARN 2 MOVE 7-12: Effectiveness of an activity stimulation program on performance of mobility and lifestyle in school-aged children with cerebral palsy

Published: 13-05-2009
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The aim of the study is to evaluate the effectiveness of an activity stimulation program on performance of mobility and lifestyle in children with cerebral palsy, in comparison with regular paediatric physiotherapy.

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

Summary

ID

NL-OMON39587

Source
ToetsingOnline

Brief title
LEARN 2 MOVE 7-12

Condition

- Movement disorders (incl parkinsonism)

Synonym
spastic children, Spastic diplegia and hemiplegia

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Activity stimulation program, Cerebral palsy, Children, Performance of mobility

Outcome measures

Primary outcome

To evaluate the intervention, measurements will be performed directly before randomization, after four months, after six months (end of intervention) and after one year (six-months follow-up).

Primary outcomes are performance of mobility (StepWatch activity monitor + activity diary, activity questionnaire[AQUA, FMS]), sports participation (CAPE), intention towards physically active lifestyle (stage of change).

Secondary outcome

Fitness(submaximal and maximal cycle test, Wingate sprinttest on a stationary bicycle, muscle strength measured with handheld dynamometry)

Capacity of mobility (sit-to-stand, attaining stand from half kneel stand, lateral step up test, 1 minute walktest, GMFM domain D,E [standing, walking, running])

Social participation (Life-Habits kids)

Health-related quality of life (CP-QOL and fatigue scale [MFS])

Self-concept (SPPC)

Study description

Background summary

Children with CP show reduced levels of physical activity compared to typically developing peers. Especially in CP children, physical activity is important, since it may prevent a decrease in mobility and decreases the risk for secondary complications due to inactivity.

Study objective

The aim of the study is to evaluate the effectiveness of an activity stimulation program on performance of mobility and lifestyle in children with cerebral palsy, in comparison with regular paediatric physiotherapy.

Study design

A six-months single blinded randomized controlled clinical trial with a six-month follow-up will be performed in local centres for paediatric physiotherapy between June 2009 and October 2011. Participants are randomised in either the control group or the experimental group. The control group follows their regular physiotherapy and the experimental group follows the activity stimulation program.

Intervention

The intervention is an activity stimulation program that consists of: 1) physical group training (4 months), and parallel, 2) a life style intervention (6 months). Group training consists of muscle strength, aerobic and anaerobic exercises. The lifestyle intervention includes home-based mobility training and counselling sessions towards a more active lifestyle. Content of the lifestyle intervention is individually defined. Physical group training takes place in local centres for paediatric physiotherapy. Home-based physiotherapy and counselling will be offered at home.

Study burden and risks

It is hypothesized that the activity stimulation program increases performance of mobility in children with CP. Muscle soreness is likely to occur but is expected to be temporary. 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

Spastic cerebral palsy
Able to walk with or without assistive device
7-13 years old

Exclusion criteria

Surgery <6 months ago or botuline toxine treatment <3 months ago
Contraindications or other medical conditions that may interfere with physical training
Children who visit secondary school

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:	Completed
Start date (anticipated):	31-08-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	13-05-2009
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-02-2011
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	26-03-2014
Application type:	Amendment
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	NL26539.029.09