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

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An activity stimulation program improves mobility performance and fitness in children with cerebral palsy.

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

Samenvatting

ID

NL-OMON20985

Bron
Nationaal Trial Register

Verkorte titel
LEARN 2 MOVE 7-12

Aandoening

cerebral palsy, training, physical activity, counseling, children

Ondersteuning

Primaire sponsor: University Medical Center

Overige ondersteuning: ZonMw
Phelpsstichting
JohannaKinderfonds
Revalidatiefonds
Kinderfonds Adriaanstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Performance of mobility:
1. Physical activity measured by 7-days accelerometry (Stepwatch);
2. Self reported activities (CAPE, AQUA, Functional Mobility Scale).

Toelichting onderzoek

Achtergrond van het onderzoek

BACKGROUND:
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.

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.

PARTICIPANTS:
A total of 50 ambulatory children (age 7-12 years) with cerebral palsy, GMFCS I-III (walking with or without walking aids).

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 and special schools for disabled children 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). The lifestyle intervention includes home-based mobility training and counselling sessions towards a more active

lifestyle. Content of the lifestyle intervention is individually defined.

MEASUREMENTS:
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, questionnaires). Secondary outcomes are fitness, capacity of mobility, participation, quality of life, fatigue and self-concept.

Doel van het onderzoek

An activity stimulation program improves mobility performance and fitness in children with cerebral palsy.

Onderzoeksopzet

1. Pretetst at baseline;

2. Fitness tests at 4 months;

3. Fitness and physical activity at 6 months;

4. Follow-up measurement at 12 months.

Onderzoeksproduct en/of interventie

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.

An activity stimulation program consisting of:

1. Physical group training (4 months), and parallel;

2. A tailored life style intervention (6 months).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 7 to 12 years;

2. Diagnosis spastic cerebral palsy based on published diagnostic criteria (2);

3. Able to walk with or without assistive devices, that means, class I to III on the GMFCS.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. If they underwent surgery (<6 months ago) or botuline toxine treatment (<3 months ago);

2. If they have cardiovascular contraindications or other medical conditions that may interfere with physical training;

3. If they are unable to follow simple instructions;

4. Have behavioural problems that interfere with participating in a group training;

5. Have predominant dyskinetic or atactic movement disorder.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2009
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-11-2009
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	NL1982
NTR-old	NTR2099
Ander register	METC VUmc : 2009/14
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
not yet