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

No registrations found.

| | |
|---|---|
| **Ethical review** | Positive opinion |
| **Status** | Recruiting |
| **Health condition type** | - |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON20985

**Source**
NTR

**Brief title**
LEARN 2 MOVE 7-12

**Health condition**

cerebral palsy, training, physical activity, counseling, children

### Sponsors and support

**Primary sponsor:** University Medical Center

**Source(s) of monetary or material Support:** ZonMw
Phelpsstichting
JohannaKinderfonds
Revalidatiefonds
Kinderfonds Adriaanstichting

## Intervention

## Outcome measures

### Primary outcome

Performance of mobility:

1. Physical activity measured by 7-days accelerometry (Stepwatch);

2. Self reported activities (CAPE, AQUA, Functional Mobility Scale).

### Secondary outcome

1. Capacity of mobility (GMFM-66 and functional leg strength, walking ability);

2. Fitness (isometric muscle strength, anaerobic capacity, aerobic capacity);
3. Health related quality of life and fatigue;

4. Self concept.

# Study description

### Background summary

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.

**Study objective**

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

**Study design**

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.

**Intervention**

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).

## Contacts

**Public**
Postbus 7057
Leontien Wely, van
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4443063
**Scientific**
Postbus 7057
Leontien Wely, van
Amsterdam 1007 MB
The Netherlands
+31 (0)20 4443063

## Eligibility criteria

### Inclusion criteria

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.

### Exclusion criteria

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.

# Study design

## Design

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

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruiting |
| Start date (anticipated): | 01-09-2009 |
| Enrollment: | 50 |
| Type: | Anticipated |

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 10-11-2009 |
| 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 | NL1982 |
| NTR-old | NTR2099 |
| Other | METC VUmc : 2009/14 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Study results

**Summary results**
not yet