

# The effect of Targeted Training Therapy(TTT) on children with Cerebral Palsy

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Objective is to study the effect of Targeted Training Therapy on balance control in children with Cerebral Palsy.

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Congenital and peripartum neurological conditions
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON30417

### Source

ToetsingOnline

### Brief title

Targeted Training Therapy in CP

### Condition

- Congenital and peripartum neurological conditions

### Synonym

Cerebral Palsy, Perinatal Brain Damage

### Research involving

Human

### Sponsors and support

**Primary sponsor:** Revalidatiecentrum Het Roessingh

**Source(s) of monetary or material Support:** Innovatiecentrum Revalidatietechnologie

## Intervention

**Keyword:** Balance, Cerebral Palsy, Function, Targeted Training Therapy

## Outcome measures

### Primary outcome

Balance (COP analysis and FRT)

Functional skills (GMFM)

Status of ambulence at home (MoVra)

### Secondary outcome

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## Study description

### Background summary

Normal controle of balance is an important condition to develop functions and skills like arm-hand cordination, sitting, standing and walking. Many children with Cerebral Palsy (CP) have problems with active balance controle through which developing these functions and skills are affected.

Targeted Training Therapy is a structured physical therapy treatment to get active balance control based on biomechanical principles during standing.

Targeted Training Therapy and the required equipement is developed by Dr. P. Butler and Mr. R. Major.

### Study objective

Objective is to study the effect of Targeted Training Therapy on balance control in children with Cerebral Palsy.

### Study design

A pilot randomised clinical trial with 20 children with Cerebral Palsy. The intervention group and the control group will each consist of 10 participants. The intervention in the form of TTT will last for 6 monts. Measurements will be made on 4 occasions, namely, initial (T0), after completion of the therapy (T3), one in between (T2) and the last 3 months after the therapy is ended (T4). Measurement instruments are Centre of Pressure analysis (COP) with a Functional

Reach Test (FRT), the Gross Motor Function measure (GMFM) and the Mobility Questionnaire (MoVra).

## **Intervention**

The intervention (Targeted Training Therapy) will be carried out 5 times a week in a group for 6 months. Part of the TTT is that the participants are standing in a standing equipment. The control group has no TTT. Both intervention- and the control groups will receive normal physical therapy treatment during the period.

## **Study burden and risks**

There is minimal risk for the participants

The load of measurements at the different moments is low for participants.

Frequency (5 times a week) and total duration of the intervention(6 months) can be experienced as much. Information about frequency and duration is given before start of the investigation. There will be regular feedback with parents and teachers about the load of the intervention for the children.

## **Contacts**

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## **Trial sites**

### **Listed location countries**

Netherlands

## Eligibility criteria

### Age

Children (2-11 years)

### Inclusion criteria

Cerebral Palsy diagnosis,

GMFCS level 2, 3 and 4

Hagberg diagnosis: spastic diplegia or tetraplegia

Age: 2 to 12 years

Mobility: shoulders: movements above 90 degrees should be possible

Hips: maximal flexion deformity is 20 degrees

Knees: maximal flexion deformity is 10 degrees

Mental level of the child: he/she understands the tasks and can carry them out. Interactive playing is possible. Bearing the load should be possible for the child and his parents.

### Exclusion criteria

Severe epilepsy

Other interventions like operations or botox injections in the past half year or in the coming half year.

Severe structural deformities of muscles and joints

Severe athetose

## Study design

### Design

Study phase: 2

Study type: Interventional

Intervention model: Parallel

Allocation: Randomized controlled trial

Masking: Open (masking not used)

**Primary purpose:** Treatment

## Recruitment

NL  
Recruitment status: Will not start  
Start date (anticipated): 02-01-2007  
Enrollment: 20  
Type: Anticipated

## Ethics review

Not approved  
Date: 17-10-2006  
Application type: First submission  
Review commission: METC Twente (Enschede)

## 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	NL14324.080.06