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

Published: 18-07-2007
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Objective is to study the effect of Targeted Training Therapy on balance control in children with Cerebral Palsy.

Ethical review	Not approved
Status	Will not start
Health condition type	Congenital and peripartum neurological conditions
Study type	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 ambulance 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 Trainng 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. Ther will be regular feedback with parents and teachers about the load of the intervention for the children.

Contacts

Public
Revalidatiecentrum Het Roessingh

Roessinghsbleekweg 33
7522AH Enschede
Nederland
Scientific
Revalidatiecentrum Het Roessingh

Roessinghsbleekweg 33
7522AH Enschede
Nederland

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 flectiondeformity is 20 degrees
Knees: maximal flectiondeformity 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 botoxinjections 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