LEARN 2 MOVE 2-3: efficacy of child-focused intervention and context-focused intervention on the performance of mobility-related, and self-care activities in toddlers (2-3 years) with cerebral palsy.

No registrations found.

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

Summary

ID

NL-OMON22470

Source
Nationaal Trial Register

Brief title
LEARN 2 MOVE 2-3

Health condition

Cerebral Palsy, Children, Intervention,
Daily functioning

Cerebrale parese, Kinderen, Interventie, Dagelijks functioneren

Sponsors and support

Primary sponsor: - Rehabilitation Centre De Hoogstraat, Centre of Excellence for Rehabilitation Medicine Utrecht
- Univeristy Medical Center Utrecht
Source(s) of monetary or material Support: - ZonMW, The Netherlands organization for

helath Reserach and development
- Phelps Stichting
- Johanna Kinderfonds
- Stichting Rotterdams Kinderrevalidatie Fonds Adriaanstichting
- Revalidatiefonds

Intervention

Outcome measures

Primary outcome

Capability of functional skills in a natural environment (Pediatric Evaluation of Disability Inventory - Functional Skill Scale).

Secondary outcome

1. Performance of mobility-related activities and self-care-related activities (Pediatric Evaluation of Disability Inventory - Caregiver Assistance Scale);

2. Amount of successful reached goals (Canadian Occupational Performance Measure);

3. Gross motor function (Gross Motor Function Measure);

4. Participation of the child in daily actvities (Preschool Children’s Assessment of Participation and Enjoyment);

5. Quality of life of the child (TNO-AZL Preschool Children Quality of Life Questionnaire);

6. Parental stress (Nijmeegse Ouderlijke Stress Index – Kort);

7. Empowerment of the family (Family Empowerment Scale);

8. Participation of the family (Participation questionnaire);

9. Quality of life of the parents (CBS Vragenlijst kwaliteit van leven ouders);

10. Family-centeredness of care (Measure of Processes of Care – NL and Measure of Processes of Care for service providers).

Study description

Background summary

To provide the best intervention, it is necessary to understand which interventions are effective and why these interventions are effective. Little is known about the efficacy and the working mechanisms of interventions for children and adolescents with cerebral palsy. The aim of the present study is to evaluate the efficacy and working mechanisms of a child-focused or a context-focused intervention approach in improving daily functioning of children (2-3 years) with cerebral palsy and their families.
94 Children with cerebral palsy (GMFCS I-IV), 2 to 3 years, and their parents and therapists will participate in this multi centre, randomized intervention study. Children will receive either child-focused, context-focused or regular care intervention during a 6 month study-intervention, with a minimum of 18 sessions. Thereafter all participants return to their regular care intervention. Measurements will be done immediately after randomization, 6 months after the start of the intervention, and 9 months after start of the intervention. The primary outcome of the study is the capability of functional skills in a natural environment. Secondary outcomes are performance of mobility and self-care related activities, amount of successful reached goals, gross motor function, participation, and quality of life.
In addition the working mechanisms of child-focused and context-focused interventions will be examined. We will explore variables like family variables, that might be related to the efficacy of the intervention, and that might explain possible variability between children. Moreover, to get more insight into the working-mechanisms of the interventions, a part of the parents will be interviewed on their experiences with the interventions.

Study objective

N/A

Study design

Baseline, and after 6 and 9 months.

Intervention

The children who participate in the study will receive either child-focused, context-focused or regular care intervention during a 6 month study-intervention period. Thereafter all participants return to their regular care intervention. During the 6 month study-intervention period, all children will receive at least 18 sessions of intervention. Maximum number of sessions in the 6 months study-intervention period will be individually based on the regular intervention frequency of the child.
Starting point of all three interventions will be to stimulate the development of the child. With this will be worked from care questions of parents and when necessary aids or devices can be used. The emphasis in the three approaches will be:

1. Child-focused: intervention approach with the emphasis on training of the (physical) capacities of the child. The therapist of the child will have a training to base the intervention of the child on child-focused intervention-principles with the child it self as most important starting point. The therapist will work primarily on the movement abilities of the child;

2. Context-focused: intervention approach with the emphasis on adapting the task or the environment of the child. The therapist of the child will have a training to base the intervention of the child on context-focused intervention-principles, in which the context will be used as primary starting point. The therapist will work primarily on the opportunities of the child in its environment;

3. Regular care: intervention approach as children receive these days. The intervention probably consist of a mix between child-focused and context-focused intervention, with the balance between child-focused and context-focused related to the therapists view. In the regular care therapists in general do not work according to one systematic approach.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children with diagnosis of cerebral palsy based on published diagnostic criteria;

2. Children classified in Levels I-IV on the Gross Motor Function Classification System (as determined by their current therapist);

3. Children enrolled in pediatric rehabilitation care, with at least both physical and occupational therapy;

4. Children receiving therapy with a frequency of at least 3 sessions per month;

5. Children aged 24 months to 47 months (2-3 years) at the time of recruitment.

Exclusion criteria

1. Children with planned surgery or medical changes during the study that may affect motor function;

2. Children whose families feel uncomfortable or unable to respond to interviews and questionnaires in Dutch (the language of all the study materials);

3. Since this an efficacy study, parents or caregivers who state that they will not be able to adhere to the treatment schedule will not be entered in the study.

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:	94
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-07-2009
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	NL1790
NTR-old	NTR1900
CCMO	NL27415.041.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A