Implicit and explicit home-based training programs for young children with cerebral palsy: process evaluation and effectiveness on bimanual performance and parental stress

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To assess fidelity (quality), dose delivered (completeness), dose received (exposure and satisfaction), recruitment and context of two newly developed upper limb home-based training programs, i.e. one based on implicit strategies and one based on...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Congenital and peripartum neurological conditions
Study type	Interventional

Summary

ID

NL-OMON44919

Source
ToetsingOnline

Brief title
COAD: home-based training programs for young children with cerebral palsy

Condition

- Congenital and peripartum neurological conditions

Synonym
spasticity, unilateral Cerebral Palsy

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht
Source(s) of monetary or material Support: ZonMW en Revalidatiefonds

Intervention

Keyword: cerebral palsy, home-based training, motor learning, upper extremity

Outcome measures

Primary outcome

Process evaluation:

fidelity (quality), dose delivered (completeness), dose received (exposure and satisfaction), recruitment and context.

Effects:

Change in performance of predetermined, individual treatment goals, focused on bimanual daily life activities (child) and therapy-related stress (parents).

Secondary outcome

Effects:

Bimanual performance (child)

Performance of predetermined, individual rehabilitation goals (child)

Satisfaction of the parents of the performance of predetermined, individual rehabilitation goals (child)

Participation (child)

Performance of upper limb functioning in daily life (child)

Quality of upper limb movements (child)

(Therapy-related) parental stress (parents)

Empowerment (parents)

Study description

Background summary

Home-based training programs can be a useful addition to institutional occupational and physical therapy for children with Cerebral Palsy (CP) for several reasons, for instance promoting parental involvement, healthcare independence and continuation of therapy aspects following institutional therapy. Even though there is a general consensus on the importance of home-based training programs, to date no evidence-based best practice exists for bimanual home-based training.

Study objective

To assess fidelity (quality), dose delivered (completeness), dose received (exposure and satisfaction), recruitment and context of two newly developed upper limb home-based training programs, i.e. one based on implicit strategies and one based on explicit strategies regarding teaching (of children by parents), in young children (aged 2 through 7 years) with unilateral spastic CP.

Study design

A mixed methods process evaluation, embedded in a multi-centre, assessor-blinded comparative case series study.

Intervention

The treatments under study consist of home-based training protocols based on either implicit or explicit strategies regarding teaching.
The interventions consist of three phases: preparation of the home-based training program (i.e. formulating treatment goals, designing the home-based training program and training of the parents); the actual home-based training program; and follow-up.

Study burden and risks

Risk associated with participation is negligible, but the burden of participation is substantial, particularly for parents. Parents will watch videos and will be home visited by a therapist at the start of the actual home-based training program. For a period of twelve weeks, parents will

practice with their child for 3.5 hours per week. The home-based training programs consist of tasks comparable to activities of daily living. During the home-based training program, the therapist will visit the children and parents at week 5 and week 9 at their home, video registrations will be made at home by the parents on a weekly basis, and parents will register training-related activities on a daily basis in digital files. Children of all treatment arms will visit a rehabilitation centre three times for a measurement session. The sessions will consist of non-invasive tests (children), and a short interview (parents). Furthermore, parents will complete questionnaires at home and will three times be interviewed. The proposed study is considered a therapeutic study.

Contacts

Public
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 HR
NL
Scientific
Universiteit Maastricht

Universiteitssingel 40
Maastricht 6229 HR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

In order to be eligible to participate in this study, a child must meet all of the following criteria: 1) clinically confirmed diagnosis of spastic CP based on published diagnostic criteria (either unilateral or extreme asymmetric bilateral), 2) being aged 2 through 7 years at the time of inclusion, 3) Manual Ability Classification System (MACS) level I-III, and 4) Gross Motor Function Classification System (GMFCS) level I-III.

Exclusion criteria

A parents-child triade who meets any of the following criteria will be excluded from participation in this study: 1) surgery or other medical interventions that may affect motor function during the study or within 9 months prior to the study, 2) participation in intensive therapy programs focusing on the upper limbs (e.g. Piratengroep) during the study, 3) inability of parents to respond to interviews and questionnaires in Dutch, 4) expected inability of parents to adhere to the home-based training protocol, 5) co-morbidity affecting arm-hand function, and 6) other indications to withhold the treatment as described.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-04-2016
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO

Date:	01-02-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-09-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	15-01-2018
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 29631
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL53670.091.15
OMON	NL-OMON29631