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

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Bimanual performance is a prerequisite for the independence and participation of young children with Cerebral Palsy (CP). Home-based training programs may be a useful addition to centre-based rehabilitation programs to improve this bimanual...

Ethische beoordeling	Positief advies
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29631

Bron
Nationaal Trial Register

Verkorte titel
COAD (Co-creation at hand: The road to independence)

Aandoening

The population under study are children with a clinically confirmed unilateral spastic cerebral palsy (CP), aged 2.5 through 7 years and their parents.

Ondersteuning

Primaire sponsor: Radboud University Nijmegen, Behavioural Science Institute
Overige ondersteuning: Under the ZonMw IIIe Programma Revalidatieonderzoek, this project is supported financially by Johanna KinderFonds, Stichting Rotterdams Kinderrevalidatie Fonds Adriaanstichting and Revalidatiefonds.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

• Performance of the child of predetermined, individual rehabilitation goals, focused on bimanual daily life activities as measured with the Canadian Occupational Performance Measure (COPM) performance scale
• Parental stress studied by qualitative data, collected through interviews

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Home-based training programs can be a useful addition to centre-based occupational and physical therapy for children with Cerebral Palsy (CP) for several reasons, for instance promoting parental involvement, healthcare independence and continuation of (motor) training following centre-based 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-training. Existing home-based programs, predominantly using explicit motor learning concepts, were shown to lead to increased stress levels of the parents and low therapy compliance, which may negatively influence the effectiveness on bimanual activity. It is expected that procedures using implicit motor learning principles do not have these adverse effects. Therefore, the present project examines which motor learning concept, i.e. implicit or explicit, is most effective to improve bimanual performance of the child and at the same time minimises stress of the parents.

Objective: The primary objective is to assess the effectiveness of two newly developed home-based training programs, in relation to each other and to usual care, in young children with unilateral spastic CP, with regard to performance of predetermined, individual rehabilitation goals, focused on bimanual daily life activities (child) and stress (parents). Secondary objectives are to assess the effectiveness of the programs on bimanual performance, the children’s’ participation and empowerment of the parents. In addition, we will perform a process-evaluation of the interventions and trial.

Study design: A three-armed, assessor-blinded, multi-centre, randomized controlled trial.

Study population: The study population consists of children with a clinically confirmed unilateral spastic CP, aged 2.5 through 7 years, and their parents.

Intervention: The treatments under study consist of home-based training programs based on either implicit or explicit strategies regarding teaching. The interventions consist of three

phases: a preparation phase in which treatment goals will be formulated, the individual home-based training program will be designed and the parents will be trained; the home-based training program; and follow-up. Children allocated to the control group (usual care), will receive care according to an individual approach (pre)determined by their treating physician.

Main study parameters/endpoints: Primary outcomes are performance of predetermined, individual rehabilitation goals, focused on bimanual daily life activities of the child as measured with the Canadian Occupational Performance Measure (COPM), and parental stress studied by parental interviews.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Risk associated with participation is negligible, but the burden of participation is substantial, particularly for parents. Parents assigned to the investigational treatments will watch videos and will make a video registration of the performance of the treatment goals by the child. Furthermore, they will be home visited by a therapist before the actual home-based training program starts. For a period of twelve weeks, parents will be training with their child for 3.5 hours per week. The home-based training programs consist of tasks comparable to activities of daily living. A therapist will visit the children and parents just before the home-based training program, at week 5 and week 9 of the program at their home, parents will make a video registration at home once per week and will register training-related activities digitally on a daily basis. Children of all treatment arms will visit a rehabilitation centre three times for a measurement session, and the parents four times. The sessions will consist of non-invasive tests (children) and a short interview (parents). Furthermore, parents will complete questionnaires at home. A purposeful sample of pairs of parents will three times be interviewed by video call. The proposed study is considered a therapeutic study.

Participants will only be recruited in the Netherlands.

Doel van het onderzoek

Bimanual performance is a prerequisite for the independence and participation of young children with Cerebral Palsy (CP). Home-based training programs may be a useful addition to centre-based rehabilitation programs to improve this bimanual performance, for example by continuation of therapy aspects in the home environment. The parents will be provided with tools to promote the bimanual performance of their child in addition to institutional therapy. This may contribute to engagement of parents in their child’s care and to healthcare independence.

Even though there is a general consensus on the importance of home-based training programs as addition to institutional programs, to date no evidence-based best practice exists for bimanual home training.

The aim of the COAD project is to examine how home-based training programs can be designed best in order to improve bimanual performance of the child and at the same time minimise the burden for the parents.

Onderzoeksopzet

As part of this study, a total of four measurement sessions will take place, i.e. at the start of phase 1 (t0), halfway phase 2 (t1), at the end of phase 2(t2) and at the end of phase 3 (t3).

Onderzoeksproduct en/of interventie

Participants will be randomly allocated to one of the following three treatment arms:

A) a home-based training program based on implicit strategies regarding teaching of the child by the parents,

B) a home-based training program based on explicit strategies regarding teaching of the child by the parents,

C) usual care.

Intervention: home-based training programs

• Supervision structure

The parents will be training with their child in their home environment. Before the intervention phase, the parents will be trained. Children of broken families will be training with two predetermined caregivers, either the parents or others. Selection of these caregivers will be based on mutual agreement between caregivers and the team at the specific centre. These caregivers will be trained prior to the intervention period and will support the children during their home training. In this protocol, these predetermined caregivers will also be referred to as ‘parents’.

Parents allocated to both home-based training programs will be coached by a multidisciplinary team, consisting of a therapist (occupational or physical therapist) and a remedial educationalist of the appropriate centre. Individual therapists will only operate within one treatment arm to prevent contamination. Allocation of a therapist to a treatment arm is based on the preference of the therapist. Remedial educationalists will operate across

treatment arms. No contamination is expected, because remedial educationalists will not coach with regard to the therapeutic content of the programs.

• Home-based training program based on implicit strategies regarding teaching:

- Training of the therapists and remedial educationalists:
The training of the therapists and remedial educationalists will be provided by members of the research team (i.e. one researcher and either one therapist or one remedial educationalist). The therapists will attend three training sessions of three hours each. The first session will focus on two topics. First, it is explained how individual treatment goals should be determined and formulated. Second the digital aspects of the home-based training programs, i.e. communication with the parents, checking the digital registrations of the home training, and supply of suggestions for activities, are addressed. The second session will focus on how the therapists should train the parents during the training session before the start of the intervention period. During the third session, information about how the parents should be coached during the intervention period will be provided. The remedial educationalists will attend one session of three hours. This training will focus on how the parents should be coached during the intervention period.

The training of the therapists and remedial educationalists will take place just before the inclusion of participants starts. One year after the first training, a refresher course of three hours will be organized for all practitioners per centre. For questions, therapists can contact the research team at anytime.

- Preparation of home-based training (phase 1):
Before the intervention period, the home-based training will be prepared. First, individual rehabilitation goals will be determined and formulated by the parents together with the therapist who will be coaching the parents during the intervention period (and, if feasible, the child). This will be accomplished using the Canadian Occupational Performance Measure (COPM). Parents will make a video registration of the child performing the treatment goals in the home situation. Based on videos of the child performing the assessments, i.e. the Assisting Hand Assessment (AHA) and the Observational Skills Assessment Score (OSAS), and the videos of the child performing the treatment goals, the coaching therapist will design an individual program according to the conceptual framework of the home-based training program to work towards the formulated goals. Moreover, an introductory meeting between the remedial educationalist and the parents will take place.

Furthermore, the coaching therapist will train the parents. The training of the parents will address four topics, i.e. the content of the home-based training program, the parent-child interaction, communication with the multidisciplinary team, and the use of modern e-health technology. This information will be provided through videos that the parents can watch at home. Parents will be asked to watch these videos in the two weeks before the first home visit of the therapist. Next, at the start of the home-based training period, a home visit by the coaching therapist of 60-90 minutes will take place, allowing the parents to ask questions and the therapist to provide further details and instructions. In case the parents have

questions that are in the remedial educationalist's domain, the remedial educationalist will be consulted by either the parents or the therapist (both in phase 1 and phase 2).

Furthermore, during this home visit, time will be spent on the execution of the home-based training in the particular home situation and practical information will be provided. Moreover, the therapist will discuss the general outline of the designed program with the parents.

- Home-based training (phase 2):

In the home-based training program based on implicit strategies regarding teaching, training will be provided by the parents of the child. Therapy will take place in the child's home environment. Parents will be coached by a therapist in how to teach new motor skills to their child.

Training will be focused on improving the performance of individual rehabilitation goals through providing training that is congruent with the context of the particular goal (i.e. task-specific therapy). This is in accordance with the latest version of the recommendations for care of children with spastic CP in the Netherlands, i.e. the 'Richtlijn Spastische cerebrale parese bij kinderen'.

Parents are supposed to practice with their child for 3.5 hours per week, for 12 weeks. These hours of training can be subdivided in periods with a minimum duration of 10 minutes. The timing of the 12 weeks will be planned in consultation with the parents.

Parents allocated to the implicit program will receive ideas for activities how to elicit bimanual performance in their child with corresponding instructions from the coaching therapist. These activities will be executed using (therapeutic) toys, provided by their coaching therapist, or everyday objects. Parents register on a daily basis what they have been doing with their child and for how long. Furthermore, once a week, parents will video-record a training session.

- Coaching of the parents:

At the beginning of each week, scheduled contact moments between the parents and their coaching therapist will take place. During these contacts, the content of the program is formulated for the upcoming week. This weekly schedule ensures that adaptations to the original plan are possible. Furthermore, a small standard evaluation will take place, in which parents have the opportunity to ask questions, discuss problems regarding the support of the child during training and indicate whether they are in need of additional coaching by the remedial educationalist. In this evaluation, also the video-recording of the training will be addressed. These contacts will be mainly over the phone, lasting approximately 30 minutes, and three times through a home visit, lasting approximately 60 minutes. As described earlier in this paragraph, the first home visit will take place just before the start of the home-based

training. Also in week 5 and week 9 home visits will take place. In the other weeks, the contacts will be over the phone. At the home visits, the therapist will provide the parents with the objects necessary for the execution of the activities in the next weeks. Therapists may schedule one additional home visit, in case they judge this necessary, e.g. for the parents to maintain the program.
Furthermore, after the second week of the home-based training, parents will be contacted over the phone, lasting approximately 30 minutes, by the remedial educationalist. During this contact, the remedial educationalist discusses with parents the process of intervention, the parent-child interaction and if applicable, their sources of stress (i.e. planning, motivational problems and/or oppositional behaviour of the child, etc) and how to cope with these. To get a clear view on the parent-child interaction during the training sessions, the weekly video registrations will be available for the remedial educationalist. For the rest of the home-based training period, no contacts between parents and remedial educationalist will be scheduled. However, in case parents have a need for this or the coaching therapist judges it necessary, a contact with the remedial educationalist can be planned.

• Home-based training program based on explicit strategies regarding teaching:

The organization of this program is similar to the previously described program. However, the teaching strategy will be different. Therefore, though the same topics will be discussed, the content of the training of the practitioners and of the parents will be different. Parents allocated to the explicit program will receive specific and elaborated exercises with the corresponding instructions from the coaching therapist. Only objects necessary for the execution of these selected exercises will be provided.

• Usual care

Children allocated to the control group, i.e. receiving usual care, will receive care according to an individual approach (pre)determined by their physician. Except for the treatment options mentioned in the exclusion criteria, i.e. planned surgery or other medical interventions that may affect motor function, and participation in intensive therapy programs focusing on the upper limbs (e.g. Piratengroep), no restrictions in treatment options will be used. In theory, children allocated to the control group will receive treatment by their usual therapist.

Similar to the home-based training programs, all activities that might affect the upper limb performance will be registered. Parents and therapists register on a weekly basis what the child has been doing that might affect upper limb performance and for how long. These registrations will be explained using an instruction video. No other training of parents or therapists will take place.

• Follow-up period (phase 3)

After the 12 weeks of either home-based training or usual care, all children will receive 12 weeks of usual care as part of the follow-up period. This care will be similar to the care mentioned in the description of the control group

Contactpersonen

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Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 2.5 through 7 years at the time of the baseline measurement;

3) Manual Ability Classification System (MACS) level I-III;

4) Gross Motor Function Classification System (GMFCS) level I-III.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A parents-child triade that 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;

6) other indications to withhold the treatment as described.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	14-04-2016
Aantal proefpersonen:	78
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	21-04-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44919
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5415
NTR-old	NTR5743
CCMO	NL53670.091.15
OMON	NL-OMON44919

Resultaten