Multi Sensory Stimulation And Priming (MuSSAP) in infants (4-12 months of age) at risk of developing Unilateral Cerebral Palsy (UCP).

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Primary objective:The following hypothesis will be tested:MuSSAP in infants 4-12 months of age with diagnosed unilateral cerebral damage, is a feasible protocol and results in an enhanced motor development as compared to Intensive Usual Care (Upper...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Encephalopathies
Study type	Interventional

Summary

ID

NL-OMON44918

Source
ToetsingOnline

Brief title
MuSSAP in infants at risk for UCP

Condition

- Encephalopathies

Synonym
unilateral Cerebral Palsy/ spasticity

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Phelps Stichting voor spastici;Johanna KinderFonds;Kinderrevalidatie Fonds Adriaanstichting

Intervention

Keyword: Infants, Multisensory stimulation, Unilateral Cerebral Palsy, Upper limb function

Outcome measures

Primary outcome

The primairy study parameter aims at development of handfunction.

At T0, T1 and T2 the following measure will be performed:

* Hand Assessment for Infants (HAI)

The HAI is currently being developed at the Karolinska Institute of Stockholm

(Sweden; Professor Eliasson and Professor Sundholm) in collaboration with the

University of Pisa. The HAI is intended to evaluate the quality of

goal-directed manual actions in infants, 3-12 months of age, at risk of

developing unilateral CP. The test procedure comprises a semi-structured

video-recorded 10-15-min play session. HAI is intended to detect and quantify

possible asymmetry between hands by providing scores for each hand seperately,

and to provide a measure of bilateral hand use (Eliasson et al. 2014).

Secondary outcome

At T0, T1 and T2, the following measures will be performed:

*

At T0 the following measures will be performed:

Hand function:

* Video-Observation Aarts and Aarts; VOAA-baby.

To assess both the overall duration and frequency of upper-limb use, the *Video

Observations Aarts and Aarts-baby* will be performed. By using structured video observations and a custom-designed software program, the tasks can be scored offline for the occurrence of specific motor behaviours (i.e. frequency) and the total duration of affected upper-limb use (Houwink et al., 2013). The VOAA-baby is in development and has therefore not been used previously in other studies .

Brain development:

Overall motor development:

* Bayley Scales of Infant and Toddler Development -Third Edition-

Nederlandse versie

(Bayley-III-NL).

The motor scale of the Bayley-III-NL will be used to assess motor development (Fine Motor subtest and Gross Motor subtest) (Steenis et al., 2014).

* Gross Motor Function Measure (GMFM).

Motor performance will additionally be assessed using the Gross Motor Function Meas-urement (GMFM). This test contains eighty-eight items grouped into five dimensions (e.g. lying and rolling, sitting, crawling and kneeling, standing, walking, running and jumping) and is sensitive to motor developmental changes over time. Typically children can perform correctly on all eighty-eight items at the age of five years (Russell et al., 2002).

* Infant Motor Profile (IMP).

The IMP is a qualitative assessment of motor behaviour in infants 3-18 months of age. The IMP is a video-based assessment of spontaneous motor behaviour of infants. The IMP evaluates motor behaviour in five domains: variation,

variability (ability to select strategies), movement fluency, movement symmetry and motor performance (Heineman et al., 2008).

A study has showed clear differences in IMP scores throughout infancy between children with and without CP diagnosed at the age of 18 months. It indicated that the predictive ability of IMP scores for CP was high (Heineman et al., 2011). The IMP has already been used an outcome measure in another studie in the same population (Sgandurra et al., 2014).

Quality of life:

* *Infant and Toddler Quality of life Questionnaire (ITQOL).

The infant/toddler quality of life questionnaire (ITQOL) is a generic parent-completed 'profile-measure' for health status and health-related quality of life of children between 2 months and 5 years old (Landgraf 1994, Raat et al. 2007).

*

At T1 the following measures will be performed:

Hand function:

* Video-Observation Aarts and Aarts; VOAA-baby.

Overall motor development:

* Bayley Scales of Infant and Toddler Development -Third Edition-

Nederlandse versie

(Bayley-III-NL).

* Gross Motor Function Measure (GMFM).

* Infant Motor Profile (IMP).

Quality of life:

* *Infant and Toddler Quality of life Questionnaire (ITQOL).

Feasibility of the intervention programme:

* Interview with parents and therapists about their experience of the interventions.

Parents and therapists will be interviewed about the experience with the interventions.

It will be a depth interview with a empirical phenomelogical approach. The question that will be asked is: 'How were the experiences with the MuSSAP intervention?'.

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At T2 the following measures will be performed:

Hand function:

* Video-Observation Aarts and Aarts; VOAA-baby.

Overall motor development:

* Bayley Scales of Infant and Toddler Development -Third Edition-

Nederlandse versie

(Bayley-III-NL).

* Gross Motor Function Measure (GMFM).

* Infant Motor Profile (IMP).

Quality of life:

* *Infant and Toddler Quality of life Questionnaire (ITQOL).

Study description

Background summary

Unilateral Cerebral Palsy (uCP) results from early brain damage. In adults, brain damage in one side of the (pre) motor cortex is associated with functional problems in the contralateral side of the body and vice versa. This is related to extensive crossings of the descending corticospinal tracts connecting the central motor systems with the musculature of the extremities. However, during the first years of our lives, crossings of the corticospinal tracts are less defined and the motor system relies on both ipsi- and contra-lateral connections to control the extremities. In children with uCP the classical development and strengthening of the crossed connections of the corticospinal tracts might be hampered. Although reorganization with ipsilateral corticospinal tracts can mediate useful hand function or near-to-normal hand function, patients with the most favourable functional outcome retain crossed projections from the affected hemisphere.
To facilitate maturation of the corticospinal tracts, it seems crucial to start early with intervention at the stage that the corticospinal tracts show high plasticity.
In this study, we propose to pilot test whether a new intervention; Multi Sensory Stimulation And Priming (MuSSAP) can be applied in clinical practice in infants 4-12 months of age with diagnosed unilateral cerebral damage having increased risk on the development of unilateral cerebral palsy. In the MuSSAP training both arms and hands will be stimulated when no clinical signs of an asymmetry in upper extremity motor functioning is visible.
With no clear asymmetric development of arm and hand function there could be a risk for the potentially preferred hand lagging behind in motor development when only the potentially affected arm and hand would be stimulated. However, when there are clear clinical signs for already existing asymmetry in upper extremity function, the intervention will focus on the less functioning arm and hand.
The arm and hand will be stimulated in a multisensory rhythmically synchronous way. In the meanwhile attention benefits from multisensory congruent signals, particularly if this congruency involves rhythmical similarity. Attention influences the sensitivity of neurons to detect sensory activity and the ability of neurons to detect sensory stimulation. Formation of neural pathways is facilitated by increasing activity in (new) functional neural circuits.
During the multisensory stimulation, motor actions of both arms and hands will be provoked. In contrast to the primary focus on motor skill acquisition in functional training, Multi Sensory Stimulation And Priming (MuSSAP) aims to enhance motor learning by stimulating the perception-action loop, thus improving binding within neural circuits involved in the early developmental stages of establishing goal-directed movements.

Study objective

Primary objective:

The following hypothesis will be tested:
MuSSAP in infants 4-12 months of age with diagnosed unilateral cerebral damage, is a feasible protocol and results in an enhanced motor development as compared to Intensive Usual Care (Upper Limb).Secondary Objective(s):
* Assessment of feasibility of the intervention:
Can the MuSSAP intervention and procedures be successfully executed and delivered to the participants?
* Assessment of feasibility of the study design and procedures:
Scrutinizing inclusion and exclusion criteria, recruitment feasibility, scrutinizing the appropriateness of the outcome measures
* Assessment of acceptability:
Suitability of the intervention and the study procedures from the perspective of the participants
* Determining effect sizes for a future full-scale RCT and clinical relevance: specific hypothesis to be tested:
o Infants at risk for uCP in the MuSSAP intervention group will show a trend to higher scores on the outcome measures on three moments in time (T0, T1, T2) then infants at risk for uCP in the Intensive Usual Care intervention group.
o Typically developing infants will show a trend to higher scores on the outcome measures on three moments in time (T0, T1, T2) then infants at risk for uCP.

Study design

Design:
The study design is a pilot case- control study with three measuring moments, T0, T1, T2.

Intervention

MuSSAP
In contrast to the primary focus on motor skill acquisition in functional training, Multi Sensory Stimulation And Priming (MuSSAP) aims to enhance motor learning by stimulating the perception-action loop. By presenting the infant simultaneous, rhythmic visual, auditory and tactile input, we aim to increase attention and to compensate diminished activations in the perception-action loop, thus improving binding within neural circuits involved in the early developmental stages of establishing goal-directed movements.
In the MuSSAP training both arms and hands will be stimulated when no clinical signs of an asymmetry in upper extremity motor functioning is visible.
With no clear asymmetric development of arm and hand function there could be a risk for the potentially preferred hand lagging behind in motor development when only the potentially affected arm and hand would be stimulated. However, when there are clear clinical signs for already existing asymmetry in upper extremity function, the intervention will focus on the less functioning arm and hand.

In the MuSSAP intervention custom made therapy material will be used to provide rhythmical congruent multisensory stimulations to both arms of the infants. During the multisensory stimulation, motor actions of the arm and hand will be provoked. The MuSSAP intervention consists of 30 minutes (divided in 3 periods of 10 minutes each) of stimulation each day for an 8-week period, conducted by the parents in the home environment. Once a week a physical or occupational therapist from a therapy practice in the neighbourhood of the infant, will provide the intervention to the infant and will give instruction and tips to the parents on how to stimulate their child following the principals of the MuSSAP intervention.
Coaching of parents and therapists will be performed by the occupational therapist of the Sint Maartenskliniek. This will be realised through analysing video recordings of the intervention in the home environment once a week.

Intensive Usual Care (Upper Limb)
The Intensive Usual Care (Upper Limb) intervention is a more intensive (in duration and frequency) version of standard Usual Care with focus on the motor development of the affected upper extremity. This intervention consists of 30 minutes (divided in 3 periods of 10 minutes each) of remediating impairments practicing specific age related movements and skills, each day for an 8-week period, conducted by the parents and once a week by a physical or occupational therapist in the home environment. Upper extremity motor activities like reaching, grasping, pulling and taking support are practiced. Coaching of parents and therapists will be performed by the occupational therapist of the Sint Maartenskliniek. This will be realised through analysing video recordings of the intervention in the home environment once a week.

Co-intervention
In both intervention groups infants will additionally receive pediatric physical therapy in the home environment (usual care). Therapists identify the impairments underlying a functional limitation (e.g. tone, posture, range of motion), and provide therapy to remediate the impairments practicing specific age related gross motor movements and skills. Functional mobility activities like rolling, crawling, standing and walking are practiced and also stretching of muscles will be part of the intervention. Parents will receive information about eating, drinking, sleeping positioning, seating positioning etc.

Study burden and risks

The burden the participants will experience exists of the measurements that will be done at three moments (T0, T1, T2) in the study, and of the intervention itself. Measurements will be conducted in the home environment of the participants. The measurements can be performed in a trusted environment for the infants and therefore the burden will be as low as possible. There are no risks involved in all the measurements and the intervention.
At all times the comfort of the participant will be taken into account. *

Parents will be asked to fill out a questionnaire at T0, T1 and T2. At T2 parents will be interviewed about the experiences with the intervention. During the intervention period parents have to video record the intervention on a daily basis and will be asked to fill out a registration form about what has been practiced in the intervention session.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

* Born preterm suffering from unilateral periventricular haemorrhagic infarction with involvement of the corticospinal tracts
* Born term suffering from unilateral middle cerebral artery stroke with involvement of the corticospinal tracts
* ±4 months of age (time the infant starts to reach with at least one hand) to 10 months of age (age corrected in case of prematurity)

Exclusion criteria

* Severe epilepsy
* Severe sensory impairments (blindness, deafness)
* Children with clinical signs of bilateral involvement
* Inability of parents to respond to interviews or questionnaires in Dutch
* Expected inability of parents to adhere to the home-based protocol

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-06-2016
Enrollment:	24
Type:	Actual

Ethics review

Approved WMO Date:	10-08-2015
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	30-03-2016
Application type:	Amendment

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-04-2017
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

No registrations found.

In other registers

Register	ID
CCMO	NL52823.091.15