Electroencephalography (EEG) and Diffusion Tensor Magnetic Resonance Imaging (DT-MRI) correlates of motor behaviour in children and adolescents with unilateral Cerebral Palsy (uCP): effects of intervention

Published: 11-07-2013
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Main group:EEG/ERP study (children and adolescents 4-17 years old)To quantify the effects of different intervention programs (mCIMT; BiT; combined mCIMT-BiT) on functional cortical processes involved in different aspects of motor behavior (i.e....

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Congenital and peripartum neurological conditions
Study type	Observational non invasive

Summary

ID

NL-OMON38974

Source
ToetsingOnline

Brief title
EEG & DTI in uCP * effects of intervention

Condition

- Congenital and peripartum neurological conditions

Synonym
unilateral Cerebral Palsy / spasticity

Research involving

Human

Sponsors and support

Primary sponsor: Radboud Universiteit Nijmegen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: DT-MRI, EEG/ERP, effects of interventions, unilateral Cerebral Palsy

Outcome measures

Primary outcome

Main group:

Event Related Potential (ERP) components from the ongoing EEG in reaction to different visual stimuli and consecutive motor responses (pressing a large button) during several simple tasks. Tasks are directed at the use of either the non-affected or the affected hand/arm. Results from stimulus-response pairs demanding the use of the non-affected hand will be compared with results from stimulus-response pairs demanding the use of the affected hand. In addition, results before and after intervention will be compared.

Sub group:

Anatomical integrity of the corticospinal tract will be measured by diffusion tensor DT-MRI and subsequent tractography of both ipsi- and contral-lateral hemispheres with respect to both the affected and non-affected hand/arm. These DTI measures (fractional anisotropy FA , mean diffusivity MD) will be compared with EEG/ERP parameters and clinical observation of the hand capacity. In addition, results before and after intervention will be compared.

Secondary outcome

Demographic variables including gender, age and co-morbidity.

Study description

Background summary

Children with unilateral Cerebral Palsy (uCP) use their affected side less than their non-affected side. Several intervention programs have been developed to increase hand/arm capacity of the affected side. It has been proposed that a lasting increase in hand/arm capacity of the affected side due to these interventions can be largely ascribed to cortical reorganization.
Magnetic Resonance Imaging (MRI) research in hemiparetic patients recovering from a Cerebral Vascular Accident (CVA) indeed showed anatomical changes in the neural substrate after intervention. However, to our knowledge, the effects of intervention on the neural substrate of children with unilateral CP have not yet been systematically studied. Such a study would be especially valuable because these children have acquired their motor deficit very early in life and therefore are fundamentally different compared to the adult hemiparetic patients. Thus, with respect to rehabilitation, these children have to learn and develop new skills unlike older CVA patients whose aim it is to regain skills.
Recent brain imaging techniques provide an excellent way to study the involved anatomical structures underlying the clinical syndrome of CP with a high spatial resolution. Therefore, in our research, we first of all aim to obtain Diffusion Tensor Imaging (DTI) during MRI scanning to determine the white matter anatomy of the cortico-spinal tracts of both ipsi- and contra-lateral hemispheres in relation to the affected side before and after an intervention. The (remaining) integrity of these tracts has been associated with outcome of intervention.
In addition, we would like to determine the effects of intervention on functional cortical processes involved in motor behavior (i.e. response selection, response initiation and response inhibition). A suitable method to map functionality of cortical areas is to measure the EEG and Event Related Potentials in the ongoing EEG related to i.e. sensory stimulation and motor behavior.
Combined DT-MRI and EEG/ERP research can provide good insight in both anatomical and functional aspects of the neural substrate involved in motor behavior before and after different intervention programs.
We expect that our currently proposed research will lead to clinically relevant information with respect to tailored treatment programs for individual children. Because we propose to study unilaterally affected children, comparing affected and non-affected side before and after intervention, there is no need

to include a group of typically developing children.

Study objective

Main group:
EEG/ERP study (children and adolescents 4-17 years old)
To quantify the effects of different intervention programs (mCIMT; BiT; combined mCIMT-BiT) on functional cortical processes involved in different aspects of motor behavior (i.e. response selection, response initiation, and response inhibition).

Sub group:
DT-MRI study (adolescents 12-17 years old)
To determine parameters by means of Diffusion Tensor MRImaging (DT-MRI) and subsequent tractography. Main aim is to quantify the anatomy of the cortico-spinal tracts from both the ipsi- and contra-lateral hemispheres in relation to both the affected and non-affected hand/arm. The remaining integrity of these tracts has been previously related to intervention outcome.

Study design

The study is designed as an quasi experiment, in which the affected and non-afected side before and after intervention all serve as within subject variables.

Intervention

Regular care

Study burden and risks

Main group:
The amount of discomfort which the participants will experience is minimal and exists of the placement of a 32-channel EEG-cap and the participation in different, playful computer-game-like tasks each of about 5 till 10 minutes. In our previous pilot, it appeared that children enjoyed to participate in these computer-game-like tasks.
There are no risks involved with EEG research. The duration will be maximally 30 minutes for EEG preparation (approximately 20-30 minutes). During the adjustment of the EEG electrode cap, the participant has the opportunity to watch a cartoon DVD on a laptop. After preparation, the computer tasks will last maximally 45 minutes (including breaks).
The measurements will be performed twice (once before intervention and once after intervention) at the location of the child*s Rehabilitation Centre and is therefore a familiar environment. Parents may be present during the measurements. Children will receive a small present after participation (value

ca 5 euro).

Sub group:
The DT-MRI measurement will last about 30 minutes and is not invasive. The adolescents must be able to lie down motionless during brief periods of scanning. There are no health-risks involved in MRI. Travel expenses will be refunded and participants will receive a gift voucher of 20 euro.

Contacts

Public
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6500 HE
NL
Scientific
Radboud Universiteit Nijmegen

Montessorilaan 3
Nijmegen 6500 HE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Main group:
Children and adolescents with unilateral Cerebral Palsy (4-17 jaar) who are registered for

either a modified Constraint Induced Movement Therapy (mCIMT- "piraten" group, n<=24), a Bi-manual Training (BiT- "Tovenaars" groep n<=24) or a combined mCIMT-BiT intervention ("Ik Hou van Holland" group n<=24) at the St. Maartens Clinic Nijmegen.;Sub group: Adolescents from the main group with unilateral Cerebral Palsy (12-17 years old) who are registered for an intervention at the Sint Maartens Clinic. Apart from the EEG study, these adolescents will also be invited to participate in the DT-MRI study.

Exclusion criteria

Severe hearing or visual disability; inability to understand the task
For MRI: presence of iron containing implants, pacemaker. Inability to keep immobile in a lying position for at least several minutes.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-06-2014
Enrollment:	72
Type:	Actual

Ethics review

Approved WMO

Date:	11-07-2013
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Approved WMO

Date:	30-06-2014
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	NL44687.091.13