Learn2Walk (Brain meets spine: the neural origin of toddler*s first step) PART II - Children with cerebral palsy

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Movement disorders (incl parkinsonism)
Study type	Observational non invasive

Summary

ID

NL-OMON49385

Source
ToetsingOnline

Brief title
Learn2Walk

Condition

- Movement disorders (incl parkinsonism)

Synonym
Cerebral palsy, spastic paresis

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit
Source(s) of monetary or material Support: NWO - Vidi

Intervention

Keyword: Cerebral palsy, Cortico-muscular coherence, Muscle synergies, Walking development

Outcome measures

Primary outcome

The primary study parameters will be the number of locomotor primitives

(derived from EMG measurements), the topological changes of brain functional

networks (derived from EEG measurements), and cortico-muscular coherence

(derived from EMG and EEG).

Secondary outcome

The secondary study parameters are kinematics and kinetics.

Study description

Background summary

Walking is a functional activity that crucially contributes to an individual*s ability to participate fully in society. Cerebral palsy (CP) is a non-progressive chronic disorder involving poor motor control, spasticity, paralysis, and other neurological problems caused by lesions in an immature brain, which affects motor development and leads to walking problems. Gait analysis of older children with CP have been thoroughly investigated, but the development of proper locomotor primitives (also known as muscles synergies) as well as the interplay between brain and muscular activity in these children is entirely unexplored. It has been shown that the coordinated muscle activation in neonate stepping is described by two locomotor primitives that are retained throughout development, and supplemented by two new ones that become manifest in Typically Developing (TD) children during the first independent steps. It*s also known that limited motor primitives are a reflection of different pathologic gait patterns as seen in CP. However, it is unknown how the development of locomotor primitives is related to topological changes of neural functional networks, the neural network dynamics and the cortico-muscular coherence in both TD and CP children. Unveiling these mechanisms of (pathological) motor development might open up new paradigms for early intervention in CP.

In order to define these new paradigms, we will need to understand how the current treatment protocols effect on locomotor primitives, neural networks and cortico-muscular coherence during walking in children with CP.

Study objective

The overall aim of the study is to characterize the underlying mechanisms of the development of walking in children with CP, through the combined measurement of electromyography (EMG) and electroencephalography (EEG). We will in particular identify the muscular and neural aspects responsible for the development of new (if any) locomotor primitives to obtain a detailed understanding of the interplay between brain and muscular activity underlying this process. In addition, we will investigate the dynamical and mechanical aspects of the pathologic gait.

Our second objective is to assess the effect of orthoses,BTA injections, SDR or physical therapy have an effect on the muscular and neural aspects of the gait pattern of children with CP.

Study design

Experimental longitudinal study (5 sessions in 2 years).

pre-post treatment study (2 sessions in 12 months)

Study burden and risks

For each subject, the full experiment will take a maximum of two to five sessions of approximately 2.5 hours, divided over 2 years. In that time children will undergo kinematics, EMG and EEG setup and they will walk on a treadmill and overground. During treadmill walking we will use a special pediatric treadmill with handle-bars in front and on the side of the child. To protect participants from falling, the parent or experimenter will support the very young and/or unstable children by arms or trunk. Total risk of side effects or adverse events during, or after the assessments and during walking on the treadmill is negligible. Periods of rest will be allowed between the measurements to prevent fatigue or accommodate focus of concentration. Furthermore, the procedure will be immediately paused as soon as the child shows any form of distress, and discontinued if the distress does not disappear. Parents will also be made aware that they are free to withdraw from the study at any time without giving a reason.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Infants aged 1 month to 3 years (corrected age);
Neurological dysfunction suggestive of development of cerebral palsy;
Cystic periventricular leukomalacia;
Uni/Bilateral parenchymal lesion of the brain;
Other structural damage of the brain.

Exclusion criteria

Functional surgery on bones and/or muscles of the legs or selective dorsal rhizotomy in the last 12 months;
Severe epilepsy.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2017
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO Date:	10-03-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	20-08-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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	NL59589.029.16