Is it possible to predict the effect of balance training based on networks in the brain in children with cerebral palsy?

Gepubliceerd: 26-08-2016 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON29671

Bron
NTR

Verkorte titel
CP-RehOP

Aandoening

Impaired balance control in children with spastic cerebral palsy

Ondersteuning

Primaire sponsor: Project leader; Prof. Dr. J.G. Becher

Principal investigator: Dr. Pieter Meyns

Sponsor: VU University Medical Center Amsterdam
Dept. of Rehabilitation Medicine
Overige ondersteuning: Subsidising party: European Commission – Marie Skłodowska-Curie action (European fellowship – proposal 660458)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The Pediatric Balance Scale (PBS) will be evaluated as the main outcome of balance control.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Children with Cerebral Palsy (CP) typically experience sensorimotor disorders such as a spastic paresis with muscle weakness, abnormal muscle activity, and ataxia. Poor balance control during standing and walking is a primary deficit in CP, which has a large impact on a child’s daily life. To improve their mobility, adequate treatment is essential. However, studies investigating the effectiveness of balance rehabilitation in CP have revealed mixed results. This is due to two reasons. First, due to the various clinical scales and experimental measures available, measuring varying components of balance, it is very complex to diagnose deficits in balance control in CP. Second, it is currently unknown which are the underlying neural causes of poor balance control in CP. Research is needed to provide fundamental insights in both areas.

Objective: First, it will be investigated which is the best diagnostic tool for imbalance in CP. Second, it will be determined whether balance training can promote balance control in CP, and whether the improvements will be maintained after a follow-up period of 6 weeks. Third, the structural and functional brain networks involved in balance control in CP will be examined and whether advances in balance control can be predicted from the neuroimaging data. Finally, it will be investigated whether advances in balance control are supported by neuroplastic changes.

Study design: RCT

Study population: Thirty-one children with spastic CP and ten typically developing (TD) children will be recruited in total (8-14 years old). All will be part of the two parts of the current proposal (A. pre-training/cross-sectional part; and B. post-training/longitudinal part). TD children are recruited to determine baseline balance deficits in CP and investigate differences in neuroplastic changes after training between both groups. Ten additional age-matched children with spastic CP will be recruited, which will receive the same assessments but will not be included in the balance training program (to compare with the group that did receive training for evaluation of the neuroplasticity after training).

Intervention (if applicable): For home-based balance training all participants will use the X-box One Kinect (Microsoft). Children will undergo a 6 week training program (5x/week, 30min/session) using Kinect games with a focus on balance.

Main study parameters/endpoints: The primary outcome of balance control that will be investigated is the Pediatric Balance Scale. Additional (secondary) balance outcomes during standing and walking will be assessed with clinical balance tests (‘balance’ and ‘running speed and agility’ subtest of the Bruininks-Oseretsky Test of Motor Proficiency, Trunk Control Measurement Scale) and experimental measures during standing and on an instrumented treadmill (kinematic, kinetic and EMG). During standing the Sensory Organization Test will be evaluated to assess the individual`s ability to use visual, proprioceptive and vestibular cues to maintain postural stability in stance, using posturography. During gait, spatiotemporal gait parameters (step width, variability measures, whole body centre-of-mass movement), the Maximum Lyapunov Exponent, gait sensitivity norm, and Foot Placement Estimator will be included to assess gait stability. Brain neuroimaging data includes structural (T1-weighted/Flair) magnetic resonance imaging (MRI), diffusion tensor imaging, and resting state-fMRI. All measured pre and post training.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Visits for baseline measurement will be scheduled simultaneously with regular consultancies if possible, to limit the number of visits to the medical center. If possible the clinical and experimental balance measurements and the MRI scans will be attempted to be performed on the same day or adjacent days. If necessary for logistic reasons or if preferred by the patient and parents/guardians the measurements can be split into separate sessions. The length of the scanning procedure proposed is about 30 minutes. Lying still for this amount of time might be burdensome for some children. Combined the balance measurements (and logistics) will take approximately 4 hours. Home-based training will be 6 weeks, some burden is expected from playing these games at home for the children and their parents. Post-training measurements (same as baseline) will be performed after the training period. Baseline as well as post-training measurements are non-invasive. Additionally, a follow-up measurement will be performed 6 weeks after the end of the training (which will include only balance assessment, no MRI). Practical relevance of the study is that this extensive evaluation of balance combined with training and brain imaging could contribute to improving balance management in CP in the (near) future.

Children with spastic CP between the ages of 8 and 14 years old will be investigated as balance control is a major issue in this population. This age range was chosen as these children are most likely sufficiently cooperative to perform the balance and MRI assessments, and will be expected to show more neuroplastic changes due to balance training then adolescents and adults.

Doel van het onderzoek

First, it will be investigated which is the best diagnostic tool for imbalance in CP.

Second, it will be determined whether balance training can promote balance control in CP, and whether the improvements will be maintained after a follow-up period of 6 weeks.

Third, the structural and functional brain networks involved in balance control in CP will be examined and whether advances in balance control can be predicted from the neuroimaging data.
Finally, it will be investigated whether advances in balance control are supported by neuroplastic changes.

Onderzoeksopzet

At baseline all primary and secondary outcomes will be measured.

6 weeks after baseline (i.e. post-training), all primary and secondary outcomes will be measured again.

12 weeks after baseline (i.e. follow-up), all primary and secondary outcomes will be measured again (expect for the MRI scans).

Onderzoeksproduct en/of interventie

For balance training the latest serious gaming product; X-box One Kinect (Microsoft) will be used.

The 31 children with cerebral palsy in the intervention group and the 10 typically developing children will undergo a 6 week training program (5x/week, 30min/session). Kinect games with a focus on balancing movements will be used (Kinect Sports Rivals, and Kinect Dance Central). The intervention will be performed at home.

The 10 children with CP in the control group will not receive the balance training.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• diagnosis of bilateral spastic CP, lower limbs more involved than the upper limbs;*

• 8-14 years;

• GMFCS level 2;*

• able to stand independently for 2 min;

• Child and Parent/guardian consent;

• Sufficient cooperation & cognitive skills: able to follow simple instructions & complete the measurements.

• MRI can be performed without general anesthesia.

* criteria for children with CP, not for the typically developing control children.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• orthopaedic surgery or other surgery in the past twelve months that might influence mobility;

• Botulinum Toxin A injections in the past six months;

• Selective dorsal rhizotomy (SDR) in the past year;

• Vestibular deficits, benign vertigo or unstable epilepsy;

• Claustrophobia;

• Pacemaker or other non-removable magnetic metal-containing objects;

• Not able to lie still for the duration of the scan;

• Not willing to hear about ‘incidental findings’, potential unforeseen, clinically relevant abnormalities found in the MRI images

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	05-09-2016
Aantal proefpersonen:	51
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	26-08-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5854
NTR-old	NTR6034
Ander register	Marie Skłodowska-Curie intra-European fellowship (European Commision) / METC VUmc : 660458 / 2016.175

Resultaten