MOTION (Mechanised Orthosis for Children with Neurological Disorders): Physiological responses to discomfort induced by the use of technological rehabilitation devices in children

Gepubliceerd: 16-12-2020 Laatst bijgewerkt: 18-08-2022

We will be able to develop a discomfort recognition algorithm for physiological responses of typically developing (TD) children and children with CP (only if the results of TD children are promising) to discomfort induced by the use of technological…

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29609

Bron
Nationaal Trial Register

Verkorte titel
MOTION discomfort

Aandoening

Children with Cerebral Palsy (and Typically Developing children)

Ondersteuning

Primaire sponsor: Sint Maartenskliniek Nijmegen
Overige ondersteuning: Interreg 2Seas

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome measures are the physiological parameters, measured with the CAPTIV system. The CAPTIV system measures respiration rate, 3D movement, electrodermal activity, skin temperature, and heart rate. Based on the measurements, an algorithm will be developed to assess the level of discomfort.

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: During the last years, many new technologies have been developed for children's rehabilitation, such as treadmills in combination with a virtual environment, robotics, and exoskeletons. Interventions using these technological devices can improve walking function, endurance, and gross motor function in children with Cerebral Palsy (CP) and induce a more intensive and task-specific exercise, which can improve the engagement of children. However, the technological devices may also cause discomfort in children, because they are not used to these forms of therapy and it may cause pain, fear, unpleasant feelings or friction of parts of the technological devices to the body. Until now, mostly subjective measurement instruments are used to measure discomfort during children's rehabilitation. However, many children with CP also have cognitive problems. Therefore, it can be difficult to complete the questions and to express discomfort. Physiological parameters, such as heart rate, blood pressure, and respiratory rate are altered during discomfort or stressful situations. Some tests exist to generate stress in adults population during for example free speech in front of an audience or while keeping a hand in cold water (Trier Social Stress Test, Mental Arithmetic Stress Test, Socially Evaluated Cold Pressor Test). However, these tests are not adapted to children and are performed while subjects are seated and standing still while these parameters are affected by physical activity. Measuring physiological parameters during training situations can be integrated into the new rehabilitation technologies by use of smart garments. In this way, it is easy to use during training with a minimal impact on children.

Objective: The primary goal of this research project is to study physiological responses of typically developing (TD) children and children with CP to discomfort induced by the use of technological devices. The obtained data will be also used to develop a discomfort recognition algorithm.

Study design: Experimental study

Study population: Typically developing children (n=6) and, if the results of TD children are promising, children with Cerebral Palsy (n=6) will be included as well, all aged 12 to 14 years.

Main study parameters/endpoints: The primary outcome measures are the physiological

parameters, measured with the CAPTIV system including respiration rate, 3D movement, electrodermal activity, skin temperature, and heart rate, which will serve as input for a discomfort recognition algorithm to measure the level of discomfort.

Doel van het onderzoek

We will be able to develop a discomfort recognition algorithm for physiological responses of typically developing (TD) children and children with CP (only if the results of TD children are promising) to discomfort induced by the use of technological devices during walking.

Onderzoeksopzet

Data will be collected on one time point.

Contactpersonen

Publiek

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Rosanne Kuijpers

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Wetenschappelijk

Sint Maartenskliniek
Rosanne Kuijpers

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

TD children:
- Aged 12 to 14 years old

Children with CP (only if the results of TD children are promising):
- Aged 12 to 14 years old

- Diagnosis of CP
- GMFCS level I or II

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

TD children:
- Motor problems indicated by parents
- Visual problems not corrected by glasses
- Conditions that influence walking ability
- Epilepsy
- Experience with walking on a treadmill

Children with CP:
- Visual or cardiovascular problems
- Temporary complaints influencing walking (such as a sprained ankle or growing pains)
- Epilepsy
- Experience with walking on a treadmill

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	04-01-2021
Aantal proefpersonen:	12
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	16-12-2020
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	NL9130
Ander register	CMO Regio Arnhem-Nijmegen : 2020-6869

Resultaten