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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29609

Source
Nationaal Trial Register

Brief title
MOTION discomfort

Health condition

Children with Cerebral Palsy (and Typically Developing children)

Sponsors and support

Primary sponsor: Sint Maartenskliniek Nijmegen
Source(s) of monetary or material Support: Interreg 2Seas

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

The Visual Analog Scale will be used to indicate the amount of discomfort during the experiments. At baseline, descriptive data as age, gender, length, and weight will be collected. In children with CP, data as GMFCS level, type of CP (spastic, dyskinetic, or ataxic) and localisation (uni or bilateral) will be collected. In addition, the questionnaire “Vragenlijst voor Angst bij Kinderen” (VAK) completed by parents and child before the start of the experiment (Oosterlaan et al. 1995) to determine trait anxiety.

Study description

Background summary

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.

Study objective

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.

Study design

Data will be collected on one time point.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	04-01-2021
Enrollment:	12
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	16-12-2020
Application type:	First submission

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
NTR-new	NL9130
Other	CMO Regio Arnhem-Nijmegen : 2020-6869

Study results