Physiological responses to discomfort induced by the use of technological rehabilitation devices in children

Published: 09-11-2020
Last updated: 08-04-2024

The primary goal of this research project is to study 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...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Observational non invasive

Summary

ID

NL-OMON49063

Source
ToetsingOnline

Brief title
Discomfort induced by technological rehabilitation in children

Condition

- Neuromuscular disorders

Synonym
Cerebral Palsy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Children, Discomfort, Physiological response, Technological rehabilitation devices

Outcome measures

Primary outcome

The primary outcome measure is level of discomfort, measured with the CAPTIV system (see paragraph 8.3 of the protocol). Respiration rate, 3D movement, electrodermal activity, skin temperature, and heart rate will be determined, which will serve as input for a discomfort recognition algorithm to measure the level of discomfort.

Secondary outcome

The Visual Analog Scale will be used to indicate the amount of discomfort during the experiments.

Study description

Background summary

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 discomfort 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.

Study objective

The primary goal of this research project is to study 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. The obtained data will be also used to develop a discomfort recognition algorithm.

Study design

Experimental study

Study burden and risks

Children have to visit the Sint Maartenskliniek only once for 1.5 or 2 hours, dependent on whether they have CP or are typically developing. We expect the experiments to cause some discomfort as this is the goal of the experiments. However, all situations will be controlled and are safe. In the experiment with Charlie*s Plank, a therapist/researcher with experience in assisting patients in virtual reality will assist the child and take care he/she won*t hurt him/herself. In the experiment on the GRAIL, all children will wear a harness and cannot fall on the treadmill. All experiments can be terminated at any time when the child feels too uncomfortable or the child/parent is not willing to continue for any other reason.
The current study is group related, as it is expected that children behave differently from adults when placed in a situation that might cause discomfort. Therefore, we cannot use the results of experiments in adults to make assumptions about physiological reactions caused by discomfort in children. Consequently, this study can only be done using this patient group of children. Children will have no benefits from participating in this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Typically Developing (TD) children:
- Aged 12 to 14 years old

Children with Cerebral Palsy (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 (such as a sprained ankle or growing pains)
- 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

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	22-05-2021
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO

Date:	09-11-2020
Application type:	First submission
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	NL74870.091.20