Stretch-REFLEX down-conditIONING using feedback in children with spastic pareses

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The main goal of this study is to test the feasibility of two different operant conditioning methods to decrease hyperreflexia of children with CP/SP/HSP, using real-time visual feedback.

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

Summary

ID

NL-OMON48808

Source
ToetsingOnline

Brief title
Reflexioning

Condition

- Movement disorders (incl parkinsonism)

Synonym
Cerebral palsy, spastic children

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Technologiestichting TTW

Intervention

Keyword: Feedback, Hyperreflexia, Spastic paresis, Stretch-reflex

Outcome measures

Primary outcome

The main study parameters are the size of the hyperreflexia of the triceps surae muscles as measured using a controlled setting with mechanical perturbations, the dynamic hyperreflexia measured as the triceps surae muscular response to muscle fiber lengthening during gait and the double bump index of the triceps surae electromyographic signal before and after visual feedback.

Secondary outcome

To evaluate if sufficient intrinsic motivation can be obtained for children with CP/HSP/SP during real-time visual feedback, the level of motivation will be assessed using a translated version of the Intrinsic Motivation Inventory (IMI).

To evaluate any changes in the gait pattern resulting from EMG feedback during the functional protocol, several parameters will be analyzed:

• Changes in foot, ankle, knee and hip kinematics.

• Spatiotemporal parameters such as stride length, stride time, stance phase and step width.

• Changes in ankle, knee and hip kinetics, including negative work at the ankle, knee and hip (J/kg), positive work at the ankle, knee and hip (J/kg) and peak power generation at the ankle (W/kg).

• Changes in gait profile score (GPS): The total gait pattern will be described

by the overall gait score as measured by GPS (Baker et al., 2009).

• A series of demographic variables will be obtained including patient history, brain MRI when available, severity of limitations, used medicines, age, gender, height and weight in order to describe the population characteristics. When available, brain MRI will be used to verify the diagnosis of cerebral palsy, and DNA tests to confirm the diagnosis of HSP.

Study description

Background summary

Spastic paresis (SP) is a common motor disorder in children. The most common cause of SP is cerebral palsy (CP) where a lesion, as diagnosed with MRI, is visible in the developing brain. In some cases, no abnormalities are seen in an MRI, but genetic testing reveals a hereditary form of SP (HSP). Over 85% of children with CP, and all children with HSP, experience spasticity, also referred to as velocity dependent stretch hyperreflexia. Hyperreflexia can lead to increased energy cost of walking, as well as limitations in muscle growth. When hyperreflexia is present, medicines are often used for treatment, but this has several limitations. Therefore, other methods are necessary to decrease hyperreflexia. Training programs to decrease hyperreflexia have been developed and tested in multiple participant groups, but only few studies analyzed this for children with CP and improvements were either small or reported results were limited. Small improvements could be enlarged when new insights in motor learning are incorporated in operant conditioning methods, such as the importance of easily identifiable goals, functional training and internal motivation. Therefore, this study will test the feasibility to decrease hyperreflexia within a single session using two different methods. In both protocols visual feedback will be provided to children with CP. In one protocol feedback is given on the reflex activity during a controlled setting, in which ramp-and-hold perturbations are applied around the ankle joint. The other protocol provides feedback on muscle activity during a functional activity, namely gait. Both tests will be performed on children with CP who have hyperreflexia and experience a deviating gait pattern. This feasibility study explores the possibilities to achieve improvements within one session and should lead to a method that can be incorporated in a larger training program in follow-up studies, to decrease hyperreflexia in children with CP on the long

term and thereby decrease energy cost of walking and allow stretch on the muscles to enhance muscle growth. Additionally, the effect of commonly applied clinical treatments will be assessed. If participants are scheduled for treatments, they will be asked to participate in post-treatment measurements where we perform the same reflex measures to assess differences.

Study objective

The main goal of this study is to test the feasibility of two different operant conditioning methods to decrease hyperreflexia of children with CP/SP/HSP, using real-time visual feedback.

Study design

This is a one-site, single- or double-session, feasibility study using a within-subject repeated measures design, as well as a between group-design for the hyperreflexia measure.

Intervention

The applied intervention exist of visual feedback provided in two parts of the protocol:
In the controlled protocol, feedback is given on the size of the hyperreflexia as measured using the Dyno 2.0.
In the functional protocol, feedback is given on the pattern of the EMG signal of the calf muscles as measured during gait.
All children with CP receive the same feedback. The two protocols are presented in random order.
No typically developing children take part in the intervention part of the research.

Study burden and risks

The burden and risks are minimal as the measurements are non-invasive, painless and easy to perform. Furthermore, two feasibility studies are combined to maximize the research benefits and minimize the burdening of the participant. Combining the two experiments reduces travel time, placement of measurement equipment and time spent on clinical tests, which are necessary for both experiments. Total risk of side effects or adverse events during, or after the assessments is negligible. Periods of rest will be allowed between the measurements to prevent fatigue. Participants will also be made aware that they are free to withdraw from the study at any time without giving a reason. The participant will not benefit from the results, but they will contribute to the treatment of CP patients in the future. The study is focused on children with CP, since they often have multiple negative effects from their hyperreflexia. Furthermore, children respond differently to training than adults, hence it is

important to analyze the applicability of this method for this participant group.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- aged between 6 and 17 years
- Sufficient cognitive skills: able to follow simple instructionsPatients:
- children diagnosed with spastic uni-or bilateral CP/SP/HSP
- hyperreflexia in at least one of the triceps surae muscles
- GMFCS level I-II (gross motor function classification system)rogram

Exclusion criteria

• Functional surgery on bones and/or muscles of the legs in the last 12 months;
• Lower limbs BoNT A injection in the last 6 months;
• Selective dorsal rhizotomy surgery in the past
• Intrathecal baclofenpump
• Shortening of the gastrocnemius (more than 10 degrees plantair flexion contracture)
• Visual deficit that will hamper with the ability to see or interpret the visual feedback as assessed by the treating physician at the department;
• Behavioural problems of an extent that may impede normal subject cooperation as assessed by the treating physician at the department;
• Comorbidities that affect walking, visual or cognitive abilities (e.g. frequent epilepsy) to an extent that makes subjects unfit to participate as assessed by the treating physician at the department.

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):	24-04-2019
Enrollment:	37
Type:	Actual

Medical products/devices used

Generic name:	Dyno 2.0
Registration:	No

Ethics review

Approved WMO Date:	05-02-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	14-11-2019
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	04-05-2021
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	NL65846.029.18