Een nieuwe functionele loopvaardigheidstraining voor kinderen en adolescenten met Cerebrale Parese om het aanpassingsvermogen van het lopen te verbeteren: een exploratieve studie

Published: 12-09-2018 Last updated: 11-04-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Encephalopathies
Study type	Interventional

Summary

ID

NL-OMON46543

Source ToetsingOnline

Brief title Functional gait training in CP

Condition

Encephalopathies

Synonym Cerebral Palsy

Research involving

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Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek **Source(s) of monetary or material Support:** Aanvraag wordt ingediend bij Phelps stichting

Intervention

Keyword: Cerebrale Parese, Children, Functional gait training, Gait adaptability

Outcome measures

Primary outcome

Primary outcome measure is the gait adaptability measure with stepladdertest.

The score includes measurement time and number of failures.

Secondary outcome

Secondary outcomes are determined during an obstacle avoidance task and motor

plan and online correction tasks on an instrumented treadmill. In addition

motor control (muscle coordination) during gait will be assessed. Furthermore,

the following clinical tests are performed: a

standardized obstacle course based on the obstacle subtask of the Emory

Functional Ambulation Profile, the 10 meter walking test, functional muscle

strength test (FSM-CP). Perceived athletic competence will be measured with the

Motorische Competentiebelevingsschaal voor Kinderen(CBSK-M), Self-perception of

performance in everyday living with the Canadian Occupational Measure (COPM)

and the Quality of life with the NL-KIDSCREEN-52.

Study description

Background summary

Children and adolescents with Cerebral Palsy (CP) experience difficulties in their gait, which affects participation in ADL-activities and has negative effects on their quality of life. The current study aims to improve gait in complex, but daily, situations of children and adolescents with CP who can walk independently (GMFS I and II). Walking over level surface and with full attention is normally not an issue for these children, however, problems occur when they have to adapt their gait to changes in the environment. This is difficult, even for those with high levels of functioning. Fast and adequate adaptations of gait to the challenges in the environment is crucial for safe mobility during ADL situations and sports and games. The target group of our study participates in regular education, because of which differences with peers at school are more obvious in the busy classroom, at the schoolyard of during sports- and game activities. Parents and therapists emphazise the need to interventions that specifically focus on the improvement of this important aspect of gait.

Study objective

The main objective of this exploratory study it to determine the effectiveness of a 5-week functional gait training on the C-mill to improve gait adaptability in children and adolescents with CP. t The intervention will also be evaluated on activity and participation level and quality of life. Secondary, a first step will be made to investigate factors affecting the effect of the intervention to be able to identify who will benefit most from this functional gait training in the future.

Study design

Randomized controlled trial with a wait-list control group

Intervention

Functional gait training on the C-mill. The C-mill is an instrumented treadmill with embedded force plates. On this treadmill visual stimuli can be projected. To train gait adaptability, participants will be asked to step on targets varying their step length, step width, step symmetry, avoid obstacles, and react to acceleration and deceleration of the targets. The training consists of 10 sessions (45 minutes, two times a week during 5 weeks)

Study burden and risks

The burden and risks associated with participation are minor. The included children will be asked to perform a measurement with tests and equipment that are common in rehabilitation practice.

The participants are asked to participate in three or four measurements (depending on the group they are referred to) of maximal 2.5 hours and 10 training sessions of 45 minutes.

All tasks are playful and, in our experience, the children enjoy performing both the overground tasks and the measurements on the instrumented treadmill. The treatment is aimed at improving gait adaptability in the children and adolescents with cerebral palsy. It is hypothesized that they will benefit from participation in this study.

Because children and adolescents with cerebral palsy and GMFCS I and II experience problems with gait adaptability in daily life, it is important to include this target group. It is not possible to perform this with other patients groups, for instance adults, because the results will have no external validity to children and adolescents with CP.

Contacts

Public Sint Maartenskliniek

Hengstdal 3 Ubbergen 6574 NL **Scientific** Sint Maartenskliniek

Hengstdal 3 Ubbergen 6574 NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

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Children (2-11 years)

Inclusion criteria

- Age 6 -17 years
- Spastic, dyskinetic or ataxic Cerebral Palsy, uni- or bilateral.
- GMFCS I-II
- Referral from rehabilitation physician regarding improvement of gait

Exclusion criteria

- Surgery such as SEMLS, SDR or ITB in the past 2 years
- Botox injections in the lower extremities in the past 6 months

- When participation in the training on the C-mill is not possible due to for example epilepsy, severe visual problems, cognitive problems or temporary complaints that influence walking.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

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NL	
Recruitment status:	Recruiting
Start date (anticipated):	05-09-2019
Enrollment:	30
Туре:	Actual

Ethics review

Approved WMO	
Date:	12-09-2018
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	18-01-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	15-12-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	
Date:	20-03-2023
Application type:	Amendment
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 CCMO **ID** NL65371.091.18