Functional gait training for children and adolescents with Cerebral Palsy

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27335

Source
Nationaal Trial Register

Brief title
Gait training CP

Health condition

Cerebral Palsy

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Phelps-stichting

Intervention

Outcome measures

Primary outcome

The primary outcome is gait adaptability, measured with the Walking Adaptability Ladder test for Kids (WAL-K). Participants walk in a ladder of 10 meters, in which the targets decrease with 2 centimeters. The score on the WAL-K will be determined by means of completion time and failures during the task.

Secondary outcome

- Obstacle avoidance task on the GRAIL
- Motor plan task on the GRAIL
- Motor control during walking on the GRAIL: amount of synergies during walking based on EMG signals of the lower extremity.
- 10 meter walk test: comfortable and maximal walking speed
- Functional muscle power of the lower extremity (Functionele Spierkracht Meting, FSM-CP)
- Perceived motor competence (Competentiebelevingsschaal voor kinderen, motorische subschaal, CBSK-M)
- Quality of life (NL-KIDSCREEN-52)
- GMFCS level
- Localisation of the CP (uni versus bilateral)

Study description

Background summary

Background: Children and adolescents with Cerebral Palsy (CP) frequently experience walking problems that limit them in participation in ADL and have adverse effects on quality of life. This study is aimed at improving walking in complex, but daily situations in children and adolescents who are able to walk independently (GMFCS levels I and II). These children can usually walk quite well on uneven terrain and while being fully concentrated. However, when they have to adapt their gait to a changing environment, this may lead to problems, even for those with a high level of functioning. Quick and accurate adaptations of the walking pattern to demands of the environment is essential for safe mobility in ADL situations and during sports and play. These situations are highly prevalent in crowded classrooms, in the schoolyard, or during sports and play activities. Parents and therapists of the children in our target population have expressed the need for training specifically aimed at improving this important aspect of walking.
Design: Randomised study with an intervention and a waiting list control group.
Population: Children and adolescents with CP, GMFCS level I or II, between 6 and 17 years old.
Intervention: A walking adaptability training program (10 sessions of 45 minutes, twice a week during 5 weeks) on the C-mill. This is a treadmill with embedded force plates and projected visual context attuned to the participant’s gait pattern. The visual context evokes adjustments in foot placements. Exercises include stepping on targets with variations in step length, width and symmetry, obstacle avoidance, and following an accelerating and decelerating target area.
Primary outcome measure: Walking adaptability as measured with the Walking Adaptability Ladder test for Kids (WAL-K). Time and mistakes (touching a bar or wrong number of steps in a target) are measured.

Study objective

Children and adolescents who participate in the study will benefit from the training because their gait adaptability will improve which will have a positive effect on participation in ADL activities and their quality of life.

Study design

This randomised study has an intervention and wait list control group. Participants will be stratified based on age category (6 to 12 years and 13 to 17 years).
After the first measurement (M1) participants will be allocated in an intervention group or wait list control group by randomasation. Participants in the intervention group directly start with the intervention. After the training of 5 weeks, both groups have the measurement again (M2). After this measurement participants in the wait list control group will start with the intervention. After the training of 5 weeks, they will have the measurement again (M3-w). Three months after the intervention the participants will have the last measurement (M4) to determine the retention of the training effects.

Intervention

Children and adolescents will participate in a training on the C-mill (Roerdink & Beek, 2009 patent MotekForcelink BV) aimed at improving their walking ability. The C-mill is a treadmill on which gait adaptations can be evoked because foot placement has to be adapted to a projected visual context. The C-mill contains a force platform, so the foot placement is registered and the performance (foot placement relative to the visual context) and different gait parameters (such as step width and length) will be determined.
The interention will focus on the gait adaptability and the automation of gait adaptability. Based on findings in a previous study, the training will consist of 10 sessions of 45 minutes divided over 5 weeks, twice a week. Exercises will relate to correct stepping on targets with variation in step length, width and symmetry, obstacle avoidance, and response to accelerating and decelerating of the stepping targets. Every training session will end with a game in which points can be scored.
The outline and duration of the exercises during the intervention will be standardised and the same for all participants. The degree of difficulty of every exercise will be adapted to the individual ability of the participant.

Contacts

Public
Sint Maartenskliniek
Rosanne Kuijpers

0031243659146
Scientific

Sint Maartenskliniek
Rosanne Kuijpers

0031243659146

Eligibility criteria

Inclusion criteria

- Age 6 to 17 years
- Spastic, dyskinetic or ataxtic Cerebral Palsy, both uni and bilateral
- GMFCS level I or II.
- Referral of the rehabilitation specialist with a question concerning walking ability

Exclusion criteria

- Surgery in the last two years like SEMLS or Selective Dorsal Rhizotomy (SDR) or Intrathecal Baclofen Therapy (ITB).
- BotulinumToxin injection in the lower extremity in the last 6 months.
- If participation in training on the C-mill (a treadmill) is not possible due to for example epilepsy, severe vision problems, cognitive problems or temporary complaints affecting walking.

Study design

Design

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

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	05-09-2019
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	13-11-2019
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	NL8154
Other	METC Arnhem Nijmegen : 2018-4223

Study results