# **Gait Analysis in an iMmersive Enviroment**

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

# **Summary**

### ID

NL-OMON43026

**Source** ToetsingOnline

Brief title GAME

### Condition

• Movement disorders (incl parkinsonism)

**Synonym** Cerebral Palsy, spastic paresis

**Research involving** Human

### **Sponsors and support**

Primary sponsor: Vrije Universiteit Medisch Centrum

**Source(s) of monetary or material Support:** European Union Is Horizon 2020 research and innovation programme under the Marie Sklodowska-Curie grant agreement No 642961. Perception and Action in Complex Environments (PACE) network

### Intervention

Keyword: Cerebral Palsy, Clinical Gait Analysis, Feedback, Perturbations

### **Outcome measures**

#### **Primary outcome**

The main study parameter for Objective 1 will be the ankle kinematics,

kinetics, muscle lengths and activity; and for Objective 2 the (in)ability of

children with CP to alter their gait in response to real-time visual feedback

challenging gait modification and improve overall gait, as well as possible

compensations, quantified by changes in hip, knee and ankle kinematics and

kinetics, depending on feedback.

#### Secondary outcome

NA

# **Study description**

#### **Background summary**

Clinical gait analysis (CGA) is a useful tool for investigating gait characteristics in children with spastic paresis, closely associated with cerebral palsy (CP). Gait is a complex motor task and so understanding the cause of a specific deviation may be difficult by only observing the patient while walking at a comfortable level. Rather, additional challenges could be posed on the patient while walking to enrich the information available from CGA and allow for better understanding of the underlying gait deviations. Firstly, treadmill belt accelerations, in which a patient is passively perturbed, could be used to measure spinal reflex activity. Secondly, by challenging the patient to actively alter specific aspects of their gait using real-time feedback on dedicated gait parameters, the ability, or inability, to alter the parameter may highlight functional impairments and have useful diagnostic inferences.

### Study objective

The main goal of the study is to evaluate the feasibility of using 1) passive

treadmill belt speed perturbations to measure spinal reflex activity in the calf muscles; and 2) active real-time visual feedback on dedicated gait parameters to highlight functional impairments in children with CP. The overall objective is to establish if both modifications to CGA provide additional clinically relevant information.

#### Study design

Experimental repeated-measures design

#### Intervention

Perturbations in treadmill speed and real-time feedback of gait parameters

#### Study burden and risks

The full experiment will take one session of approximately 2 hours. In that time children will undergo a standard clinical gait analysis on a treadmill with interactive virtual reality environment, complemented with passive perturbations as well as different gait modification feedback conditions. Subjects will undergo a standard physical examination if not available from clinical practice. The risk of passive perturbations and gait modifications is negligible, as demonstrated by earlier studies. To protect participants in the unlikely event of falling, subjects will wear a safety harness during the walking trials. Total risk of side effects or adverse events during, or after the assessments and during walking on the treadmill is negligible. Periods of rest will be allowed between the measurements to prevent fatigue. Patients will also be made aware that they are free to withdraw from the study at any time without giving a reason.

# 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**

\* Children with a diagnosis of uni/bilateral spastic paresis;

\* Aged between 5 and 16 years;

\* GMFCS level I-II. (gross motor function classification system) (Palisano et al. 1997);

\* Sufficient cognitive skills: able to follow simple instructions;

\* Good walking ability, i.e. able to follow protocol walking time of 28 minutes. It will be explained to the parents/carers that they must be able to walk on the treadmill for approximately half an hour, with short breaks provided. It is expected that care givers will have a good understanding of the child\*s ability and therefore their suitability to take part.

### **Exclusion criteria**

\* Functional surgery on bones and/or muscles of the legs or selective dorsal rhizotomy in the last 12 months;

\* Lower limbs BoNT A injection in the last 6 months;

\* 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): | 13-04-2016          |
| Enrollment:               | 60                  |
| Туре:                     | Actual              |

# **Ethics review**

1.14/140

| Approved WMO<br>Date: | 06-04-2016         |
|-----------------------|--------------------|
| Application type:     | First submission   |
| Review commission:    | METC Amsterdam UMC |
| Approved WMO<br>Date: | 28-12-2016         |
| 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

ССМО

ID NL56736.029.16