Part 1. Gait analysis in typically developed children: Differences in gait and balance characteristics during self paced gait between over ground VICON 3D motion capture system and the CAREN system.

Published: 20-07-2016
Last updated: 21-04-2024

To compare gait and balance measured by the traditional 3D gait analysis system (VICON) and by the new system including a treadmill and a virtual environment (CAREN) during self-paced walking in typically developed children. In addition, a...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Musculoskeletal and connective tissue disorders congenital
Study type	Observational non invasive

Summary

ID

NL-OMON45072

Source
ToetsingOnline

Brief title
Gait analysis in typically developed children.

Condition

- Musculoskeletal and connective tissue disorders congenital

Synonym
typically developed children

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Caren, children, Gait, vicon 3D

Outcome measures

Primary outcome

First, gait characteristics as such spatiotemporal parameters (e.g. step length), 3D kinematics and kinetics of the ankle, knee and hip joint, dynamic balance parameters (e.g. margins of stability, gait variability) and muscle activity will be determined by using both gait analysis systems. Second, reference values for gait and balance parameters of typically developed children of varying age will be created (and corrected for anthropomorphic variation).

Secondary outcome

Second reference values for gait and balance parameters of typically developed children of varying age will be created.

Study description

Background summary

Threedimensional gait analysis is routinely used in regular evaluation and planning of treatment of children with mobility problems such as cerebral palsy and spina bifida. It has been shown that children with CP have to deal with high variability in trunk balance [34]. This variability in trunk balance demands extra effort and energy consumption. Abnormal fatiguiing during walking

and falling is a major problem in these affected children. A stable gait pattern is thus essential, as it provides an efficient energy consumption (less fatigued) and it reduces the chance to fall.

The traditional gait analysis system (VICON 3D motion capture system) uses selfpaced overground walking. Recently, a new system has become available at MUMC+; Computer Assisted Rehabilitation Environment (CAREN), which combines the VICON 3D motion capture system with a split belt treadmill and a virtual reality environment. This system enables to analyse several successive steps. In addition CAREN allows us to give real time feedback, providing and provides various training possibilities (e.i. gaming), which makes it attractive for children. For these reasons, we like to use CARENaren for gait analysis in children with mobility problems.

Only few studies are done comparing both systems, showing small differences in gait. However most of these studies focused on adults, and studies withon children are scarce.

Study objective

To compare gait and balance measured by the traditional 3D gait analysis system (VICON) and by the new system including a treadmill and a virtual environment (CAREN) during self- paced walking in typically developed children. In addition, a reference database for gait and balance characteristics of typically developed children of different age ranges is created for both systems, which will be used to interpret deviations in gait of children with cerebral pareses and spina bifida.

Study design

A comparative , cross- sectional propespective, single center pilot study on typically developed children of different ages. The composed age groups are based on known gait development phases throughout childhood. In each age group (3-4 years, 5-6 years, 7-8 years, 9-10 years,11-12 years, 13 years and older) 10 children will be included. The choice for these age ranges and the amount subjects relies on several assumptions: The walking speed increases in children with 10% per 2 years. Literature shows that a sample size of 10 children per age range provides reproducible outcomes. In addition, the number of participants is matched with the availability of the VICON lab and the CAREN lab.
Inclusion criteria: ambulatory, ability to walk without aid for 60 minutes and age between 3-14 years.
Exclusion criteria: Acute and/or chronic muscular skeletal disorders, interventions such as surgical treatment or botulinium toxin 6 months prior to the assessment, severerious pes plano valgus, leg length difference > 1cm, scoliosise with Cobbse angle >10°, parents or caregivers who are not proficient

in the Dutch language.

Study burden and risks

The risk of gait analysis is negligible. During the CAREN measurement, a safety harness is worn which provides protectsion against falling. The safety harness is secured with a life- line to the ceiling. The burden for the children is minimal. There is however a time burden. From start till endThe whole analysis will take approximately 2 hours. Parents will receive compensation for travelling expenses. The children will receive a present (+/- 5 euros) for participation.

Contacts

Public
Academisch Medisch Centrum

P.debyelaan 25
Maastricht 6229 HX
NL
Scientific
Academisch Medisch Centrum

P.debyelaan 25
Maastricht 6229 HX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

.- Ambulatory
- Ability to walk without aid for 60 minutes
- Age between 3-14 years
- Parents or caregivers and subject who are proficient in the Dutch language
- Willing to participate (permission from parents/care givers and subject);* Age 3-14 years;
* Willing to participate (permission from parents/care giver)

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Acute and/or chronic muscular skeletal disorder
- Interventions, such as surgical treatment or botulinium toxin 6 months prior to the assessment
- Rigid or painful pes plano valgus
- Leg length difference> 1cm (block testing)
- Clinically manifest scoliosis (curved spinal column, unequal shoulder levels, gibbus deformity when bending

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-07-2017
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	vicon 3d motek caren
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	20-07-2016
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL51929.068.14