Proof of concept functional prototype INES full exoskelet

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Neuromuscular disorders
Study type	Interventional

Summary

ID

NL-OMON53255

Source
ToetsingOnline

Brief title
Proof of concept INES exoskeleton

Condition

- Neuromuscular disorders

Synonym
Cerebral palsy, paralysis

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: Europese Unie;Interreg2Seaas

Intervention

Keyword: cerebral palsy, children, exoskeleton, proof-of-concept

Outcome measures

Primary outcome

The primary outcome measure is usability that will be measured with the System

Usability Scale (Dutch version).

Secondary outcome

In addition, performance of the defined use cases (Donning, Doffing,

Sit-to-stand, Stand-to-sit, Walk) will be described and evaluated.

Study description

Background summary

Cerebral palsy is one of the most common disabilities in childhood. Cerebral palsy is a permanent non-progressive disease, but the symptoms may become more severe over time and the impact on daily live as well. Children often experience limitations in gait and self-mobility which are associated with a lower quality of life score regarding their physical wellbeing. Robotic devices has been developed ror gait training and support during daily life for adults. However these are not suitabel for children with cerebral palsy. Therefore the aim of the MOTION project was to develop an exoskeleton(INES) for children with neurological disorders (in particular children with cerebral palsy)to improve quality of life.

Study objective

The primary goal of this research is to test the proof of concept of the functional prototype of the INES exoskeleton for children with CP in the clinic. In addition,the defined use cases (Donning, Doffing, Sit-to-stand, Stand to sit, Walk) will be evaluated.

Study design

Explorative/feasibility study

Intervention

Exploratieve/feasibility studie to evaluate the functional prototype of the INES exoskeleton.

Study burden and risks

All participants have to visit the Sint Maartenskliniek twice for 2 hours. We expect that the tests may cause some discomfort, since the participants are not used to walk in an exoskeleton. In addition it must be noted that he INES exoskeleton is a functional prototype tested in an clinical environment for the first time during development. However, all situations will be controlled and are safe. For balance control, participants are allowed to use assistive devices. In addition, tests will be performed in a robotic body-weight support system on an overhead track that allow practicing activities without the risk of falling. Furthermore, a physical therapist and technician with experiences in robotic devices will assist during the session. All experiments can be terminated at any time the participants feels too uncomfortable or the participant/parent is not willing to continue for any other reason.
The current study is group related, as the exoskeleton is developed for children with neurological disorders (for example cerebral palsy). Since children with neurological disorders are the target group, the exoskeleton should be tested in these children with walking problems such as muscle weakness, coordination impairment, spasticity and bone deformations. Since we will test the functional prototype of the INES exoskeleton in the clinic for the first time, the exoskeleton will be tested in (small) healthy young adults, before we will start testing with young adults with CP.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (16-17 years)
Adults (18-64 years)

Inclusion criteria

1) Healthy (young) adults (n=4)
-Age > 16 years old
-Weight 20-55 kg
-Height 1.34-1.60 m
-No conditions that affects walking ability
-No cognitive problems

2) Young adults with cerebral palsy (n=4)
-Age >16 years old
-Bilateral cerebral palsy
-GMFCS II-IV
-Weight 20-55 kg
-Height 1.34-1.60 m
-No severe cognitive problems
-No severe spasticity
-No severe limited range of motion in ankle, knee and hip joints.
-No severe bone deformations

Exclusion criteria

-Temporary complaints affecting walking (such as a sprained ankle)
- (Little) wounds on body parts that are in contact with the exoskeleton
-Severe secondary health conditions (such as cardiovascular problems)

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-09-2024
Enrollment:	8
Type:	Actual

Medical products/devices used

Generic name:	Inès Exoskeleton
Registration:	No

Ethics review

Approved WMO Date:	06-11-2023
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	23-05-2024
Application type:	Amendment
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL84127.000.23