Efficacy of the Myosuit for increasing daily life gait performance in the home and community setting and gait capacity in people with incomplete spinal cord injury

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Part A:The primary objective is to test the efficacy of the Myosuit, a soft exosuit, for increasing daily life gait performance in the home and community setting in people with iSCI. Secondary, the efficacy of the Myosuit program on gait capacity...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Spinal cord and nerve root disorders
Study type	Interventional

Summary

ID

NL-OMON51508

Source
ToetsingOnline

Brief title
Efficacy of the Myosuit in incomplete spinal cord injury

Condition

- Spinal cord and nerve root disorders

Synonym
Spinal cord injury, tetraplegia

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek
Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Daily life gait performance, Gait capacity, Incomplete spinal cord injury, Myosuit

Outcome measures

Primary outcome

Part A:

The primary objective is to test the efficacy of the Myosuit, a soft exosuit, for increasing daily life gait performance in the home and community setting in people with iSCI. The main study parameter is the number of minutes walking per day.

Secondary, the efficacy of the Myosuit program on gait capacity and its cost-effectiveness based on this RCT will be investigated. Finally, the usability of the Myosuit for use in home and community setting will be evaluated. For gait capacity the primary study parameter is the 10 meter walk test (10MWT) at preferred walking speed. The System Usability Scale (SUS) is the primary study parameter for usability. For cost-effectiveness quality-adjusted-life years (QALY) gain and costs will be measured.

Part B:

The primary objective is to investigate differences in gait capacity with wearing the Myosuit compared to without wearing the Myosuit by conducting

clinical tests. The primary study parameter for gait capacity is the 10MWT at preferred walking speed.

Secondary, differences in gait capacity measured on the GRAIL with and without wearing the Myosuit will be examined. The tripartite model described by Balasubramanian and colleagues will be taken as starting point. In this model, gait capacity consists of three components: stepping, dynamic balance and gait adaptability. The main study parameters are: preferred walking speed, margin of stability and precision stepping for respectively stepping, dynamic balance and gait adaptability.

Secondary outcome

Part A:

The primary objective is to test the efficacy of the Myosuit, a soft exosuit, for increasing daily life gait performance in the home and community setting in people with iSCI. Secondary study parameters are: activity intensity, length and number of gait bouts, maximal covered distance, mean and variability in spatiotemporal gait parameters, margin of stability, foot placement and Lyapunov exponent.

Secondary, the efficacy of the Myosuit program on gait capacity and its cost-effectiveness based on this RCT will be investigated. Finally, the usability of the Myosuit for use in home and community setting will be evaluated. The secondary study parameters for gait capacity are the 10MWT at maximum walking speed, the 6 minute walk test (6MWT), the mini balance

evaluation system test (Mini-BESTest), the walking index for spinal cord injury II (WISCI II) and the spinal cord injury functional ambulation profile (SCI-FAP), for measuring functional walking performance. The Dutch version of the quebec user evaluation of satisfaction with assistive technology (D-QUEST) is a secondary study parameter for usability.

Part B:

The primary objective is to investigate differences in gait capacity with wearing the Myosuit compared to without wearing the Myosuit by conducting clinical tests. Secondary study parameters for gait capacity are the 10MWT at maximum walking speed and the 6MWT.

Secondary, differences in gait capacity measured on the GRAIL with and without wearing the Myosuit will be examined. Secondary study parameters are: step length, step-length symmetry, single-support time, single-support time symmetry, hip-knee-ankle kinematics, joint moments and peak joint powers for stepping and foot placement for dynamic balance.

Study description

Background summary

People with incomplete spinal cord injury (iSCI) show often impairments and limitations related to walking dysfunction. Therefore, a common primary goal of people with iSCI is improvement of gait. Despite all the effort put in regaining gait capacity by training, gait and standing capacity and ambulation in home and community setting of many people with iSCI remain limited. As a consequence of limited gait capacity, these people are likely to develop a

sedentary lifestyle resulting in a vicious circle of walking impairments, which negatively affects daily life gait performance and quality of life. One of the options with a high potential to improve gait capacity and daily life gait performance is the use of assistive technology. Powered exoskeletons compensate for the loss of strength, however, exoskeletons are heavy and take over the entire control of the lower limbs. Patients with iSCI who have residual mobility do not take advantage of heavy exoskeletons. Light-weighted exosuits provide assistance during walking and patients do have a voluntary contribution of the leg muscles. A recently introduced lower extremity soft exosuit is the Myosuit (MyoSwiss AG). In a small sample study, participants showed an increased gait speed when using the Myosuit compared to their baseline gait speed. Moreover, a small number of training sessions was required for use in the home and community setting. In this study the efficacy of the Myosuit for increasing daily life gait performance in the home and community setting in people with iSCI will be tested. Furthermore, we will evaluate the effect of wearing the Myosuit on gait capacity.

Study objective

Part A:
The primary objective is to test the efficacy of the Myosuit, a soft exosuit, for increasing daily life gait performance in the home and community setting in people with iSCI.
Secondary, the efficacy of the Myosuit program on gait capacity and its cost-effectiveness based on this RCT will be investigated. Finally, the usability of the Myosuit for use in home and community setting will be evaluated.

Part B:
The primary objective is to investigate differences in gait capacity with and without wearing the Myosuit by conducting clinical tests. Secondary, differences in gait capacity measured on an instrumented treadmill with motion capture system, the GRAIL, with and without wearing the Myosuit will be examined.

Study design

Randomized controlled trial.

Intervention

Part A: The intervention group will receive training sessions with the Myosuit at the Sint Maartenskliniek. Thereafter, they will receive the Myosuit at their disposal at home for six weeks. The control group will receive a program of regular physiotherapy and a personalized regular training program for at home.

Part B: Participants perform clinical tests and measurements on an instrumented treadmill with and without the Myosuit.

Study burden and risks

There are no serious risks associated with participation in this study.
Clinical tests which will be performed in context of this study, are already conducted in clinical care. Participants will wear a safety harness during measurements on the GRAIL. For safe use of the Myosuit participants receive a training program from certified physiotherapists. Furthermore, where possible, a caregiver will attend minimal one Myosuit training session in order to assist the patient in the home and community setting. Participants receive the Myosuit at their disposal at home when they are able to use the Myosuit independently. If a participant have any questions about the use of the Myosuit he/she can contact by phone the researcher/physiotherapist for advice.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- People with chronic iSCI (>6 months after injury).
- Having an injury level of C or D on the American Spinal Injury Association Impairment Scale.
- Age >= 18 years.
- Need to have sufficient hand function to don and doff the Myosuit or they need a caregiver who is available to help the participant to use the Myosuit at home.
- Having reduced gait capacity due to reduced knee and/or hip strength (MRC<5).
- Must be able to stand up from a chair without deviating to the left or right side for more than 45 degrees during the movement.
- Can walk for 10 meter without the assistance of another person but can be assisted by assistive devices except knee orthoses.
- People aim to improve walking distance, walking speed or walking function.
- For the second objective of the second part of this study, only people who are be able to walk consecutively for two minutes on a treadmill without any assistive device and without using the handrails will be included.

Exclusion criteria

- Have another (neurological) disease which can influence motor performance.
- Have small wounds which can be worsened by wearing the Myosuit will be excluded.
- Taller than 195 and smaller than 150 cm.
- Body weight of more than 110 kg or less than 45 kg.
- Pregnancy.
- Flexion contracture in knee or hip in excess of 10 degrees.
- Varus malposition in excess of 10 degrees or valgus malposition in excess of 10 degrees.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-10-2022
Enrollment:	34
Type:	Actual

Medical products/devices used

Generic name:	Myosuit
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	29-06-2022
Application type:	First submission
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	ID
CCMO	NL80641.091.22