Clinical investigation on the safety and performance of the ABLE Daily to assist people with spinal cord injury in home and community settings

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The primary objective of this study is to assess the safety and performance of the ABLE Daily to perform ambulatory functions in home and community settings for people with spinal cord injury.The secondary objectives are to assess the impact of the...

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

Summary

ID

NL-OMON57428

Source
ToetsingOnline

Brief title
ABLEdailySCI

Condition

- Spinal cord and nerve root disorders

Synonym
paraplegia, Spinal cord injury

Research involving
Human

Sponsors and support

Primary sponsor: Sint Maartenskliniek

Source(s) of monetary or material Support: Universitat Politècnica de Catalunya en Sint Maartenskliniek

Intervention

Keyword: home, lower limb, powered exoskeleton, Spinal Cord Injury

Outcome measures

Primary outcome

The primary objective of this study is to confirm the safety and performance of the ABLE Daily to perform ambulatory functions in home and community settings for people with spinal cord injury.

Secondary outcome

The secondary objectives are to assess the impact of the ABLE Daily use on the perceived general health of the participants, the gait performance with the ABLE Daily using data collected from the exoskeleton, and the level of user satisfaction from participants, companions, and therapists.

Study description

Background summary

A spinal cord injury can affect the patients' ability to walk and maintain balance. As a result, paraplegic patients are often dependent on the wheelchair to move around, which means they sit a lot during the day. This results in less physical movement each day, which might have negative consequences for the mental and physical health.

With the emerging technologies, an exoskeleton could perhaps (partly) replace the wheelchair and increase the amount of physical movement in a day. At the moment, exoskeletons are only used in clinics and not yet in the home environment. To date, only one study has been published that has investigated the effect of home use the Rewalk exoskeleton. This research has shown improvements on the mental and physical health in spinal cord injury patients after only two weeks of using an exoskeleton in the home environment, but it is

still unknown what the consequences are for mental and physical health after an installed period in the home environment .

Study objective

The primary objective of this study is to assess the safety and performance of the ABLE Daily to perform ambulatory functions in home and community settings for people with spinal cord injury.

The secondary objectives are to assess the impact of the ABLE Daily use on the perceived general health of the participants, the gait performance with the ABLE Daily using data collected from the exoskeleton, and the level of user satisfaction from participants, companions, and therapists.

Additionally, exploratory endpoints are selected to observe the effect of using the ABLE Daily for ambulatory functions in home and community settings on health promotion. The change from baseline to final assessment of participant*s parameters in the following domains will be quantified:
- Cardiovascular
- Respiratory
- Muscle spasms and spasticity
- Bowel function
- Bladder function
- Body composition
- Insulin sensitivity
- Sleep quality
- Mental health and quality of life

Study design

Intervention study with 10 spinal cord injury patients.

Intervention

ABLE Daily exoskeleton use in the home and community settings.

Study burden and risks

The research is quite time-intensive. We ask the participant to practice with the exoskeleton in the clinic three times a week during the clinical period of three weeks. Once the participants have received the exoskeleton home, we expect them to walk with the exoskeleton at least three times a week for 30 minutes.

The exoskeleton can create pressure points on the skin. In addition to the

pressure points, the participant may experience joint pain or swelling because the participant is moved by the exoskeleton or because the exoskeleton has not been fitted properly. To reduce the risk of pressure points and joint pain or swelling, the skin will be examined before and after training by the therapist and at home by the buddy. In addition, the ABLE Daily has cushions at the various contact points.

When the participant moves from sitting position to standing position, a sudden difference in blood pressure can cause dizziness. This physical response is reduced when this movement is repeated more often.

Because the participant is not used to walking in an exoskeleton, the participant can easily lose balance. The participant is therefore required to use crutches or a walker that help maintain balance. In addition, the buddy must always be present when the exoskeleton is used. Despite these measures, there is still a chance that the participant will fall.

Previous research has shown that in rare cases bone fractures occur due to the use of the exoskeleton. In this study, there will be a preliminary screening to confirm that the participants have healthy, strong bones. Despite this measure, it cannot be ruled out that there is a risk of bone fractures during this study.

Exoskeletons could be suitable for improving the mobility and independence of people with physical disabilities. Previous research with a different exoskeleton has shown that there may be health benefits to walking with an exoskeleton. Reduced spasticity in the muscles was observed, less pain, improved bowel function, improved fitness and less fatigue and thus an improved quality of life. However, we cannot guarantee that participants will experience these benefits. By participating in the study, we can gain more knowledge about the application of the exoskeleton in rehabilitation, which could possibly help people who are in a similar situation as the participant.

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

At least 18 years old
Chronic SCI (>6 months)
Injury at levels T1 to L5 (AIS A to D)
Walking Index Spinal Cord Injury (WISCII) 0 till 9
Between 150-200 cm
Weight less than 100 kilograms
Capable of giving informed consent on their own
Able to train (at least) 3 days/week
Able to have at least 1 companion/buddy who can attend a minimum of two of the training sessions, besides the Final assessment, and who will learn how to assist them at home and in the community. (ideally two companions)
Proficiency in walking with the ABLE Exoskeleton
At least 8 weeks with minimal use (less than 5 sessions) of wearable robotic exoskeletons for gait assistance at the start of the study.

Exclusion criteria

High risk of fractures due to osteoporosis, a dual energy X-ray absorptiometry (DEXA)-scan at the hip, distal femur and proximal tibia T-score < -2.5 or BMD smaller/equal to 0.78 g/cm^2
Fragility fractures of the lower limbs in the last 2 years
Deterioration >3 in the International Standards for Neurological Classification of SCI (ISNCSCI) score in the last 4 weeks

Spinal instability, like spondylolisthesis
Disorders of the arms and hands that make walking with crutches impossible
Modified Ashworth Scale (MAS) >3 in lower limbs
Cardiovascular health issues which prevent the participant from training
Inability to tolerate 10 minutes of standing without clinical symptoms of orthostatic hypotension
Psychological, cognitive issues, or any other condition that does not allow a participant to follow study procedures
Medically unstable due to severe comorbidities, including any condition that a physician deems inappropriate for completing study participation
Skin problems in areas that would be in contact with the device
Height, width, weight, or other anatomical limitations (such as differences in leg length) incompatible with the device
Insufficient joint range of motion (ROM) for the device
Known pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	05-01-2025
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	ABLE Daily
Registration:	No

Ethics review

Approved WMO Date:	17-04-2025
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	NL88507.000.24