Robotic assisted balance and exoskeleton training (REACTION) in neurorehabilitation; a feasibility study

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON57403

Source
ToetsingOnline

Brief title
REACTION; A feasibility study

Condition

- Other condition
- Central nervous system vascular disorders

Synonym
Cerebrovascular accident (CVA), Spinal Cord Injury (SCI), Stroke; paraplegia

Health condition

patients with lower extremity limitations due to trauma-related injuries and/or neurologic disorders

Research involving

Human

Sponsors and support

Primary sponsor: Revalidatiecentrum Het Roessingh
Source(s) of monetary or material Support: EUREKA

Intervention

Keyword: Exoskeleton, Gait trainer, neurological disorders, rehabilitation

Outcome measures

Primary outcome

The primary outcome is DONNING and DOFFING

Secondary outcome

Secondary outcomes are:

- Gait speed

- kinematic data

- Short Form Berg Balance Scale (SFBBS)

- Short Falls Efficacy Scale - International

- Level of Assistance

Study description

Background summary

Neurological disorders, such as stroke and spinal cord injury (SCI), can affect our ability to walk and balance. Robotic devices in rehabilitation might train walking and balance capabilities in patients with neurological disorders. Recent papers and reviews have highlighted the potential of various control strategies during walking, such as assist-as-needed (AAN). A new robotic assisted balance and gait trainer (REACTION) will be designed to train walking and balance in patients with neurological disorders. REACTION is one of the first modular ambulatory balance and gait trainer that combines assist-as-needed (AAN) balance on the affected leg and provide body-weight

support

Study objective

The primary objective is to explore the effect on Donning and Doffing of REACTION and their subsystems (ABLE REGAIN and GABLE CORE) in individuals with neurological disorders. The secondary goals include:

1. To explore the effect of REACTION and their subsystems on gait speed
2. To explore the effect of REACTION and their subsystems on gait kinematics
3. To explore the effect of REACTION and their subsystems on balance
4. To explore the effect of REACTION and their subsystems on user satisfaction

Study design

Multicenter feasibility study

Intervention

Two measurement days consisting of a walking and balance tasks for each condition (no aid, regular aid, ABLE REGAIN, GABLE CORE, REACTION). The condition 'regular aid' does not have a balance task.

Study burden and risks

During the clinical tests there is a chance that subjects might lose their balance. However, the tasks that are performed during these measurements resemble tasks of daily life and short versions of commonly used balance tests in conventional rehabilitation. Therefore, the chances that performing these tasks will lead to falls are not higher compared to daily life. In addition, all included participants are independent walkers (FAC 3-4) and an investigator always walk beside the participant while performing all tasks. Gait analysis involves no extra risks to walking in daily life. Subjects can take rest between the measurements any time they like.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

In order to be eligible to participate in this study, a participant must meet all of the following criteria:
• Age > 16 years
• Able to give informed consent
• Weight < 90 kg
Stroke patients:
• first-ever ischemic or haemorrhagic stroke
• FAC score between 3 and 4
• (Sub)acute or chronic phase
SCI patients:
• Neurological injury levels ranging from C5 to T9
• Motor incomplete spinal cord injury (ASIA impairment score of C or D)
• Able to walk independently (without physical support)

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
• mild to severe cognitive problems
• Premorbid disability of lower extremity
• Skin lesions or severely impaired sensation at the hemiparetic leg

• Contraindication for mobilization, like lower limb fracture
• Insufficient knowledge of the Dutch language to understand the purpose or methods of the study
• Pregnancy

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	REACTION
Registration:	No

Ethics review

Approved WMO

Date:	09-04-2025
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
ClinicalTrials.gov	NCT06805500
CCMO	NL88875.044.25