Evaluation of RYSEN gait training in clinical practice

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

Summary

ID

NL-OMON57057

Source
ToetsingOnline

Brief title
RYSEN gait training

Condition

- Other condition

Synonym
cerebrovascular accident, paraplegia, spinal cord injury, stroke, tetraplegia

Health condition

cerebrovasculair accident en dwarslaesie

Research involving
Human

Sponsors and support

Primary sponsor: Heliomare revalidatiecentrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: body weight support, gait training, spinal cord injury, stroke

Outcome measures

Primary outcome

Experiment A & B

- Walking speed in m/s

- Step frequency in steps/s

- Step length in m

- Step width in m

- Margins of stability in m

- Muscle activity of eight muscles of the lower limb in microvolts

- Acceleration of pelvis, thigh and shank in m/s2

- Score on a purpose-made questionnaire about comfort and safety during walking

Experiment C

- Number of steps taken during training

- Net heart rate and predicted percentage of heart rate reserve

- Variability in trunk acceleration

- Rating of perceived exertion (RPE) (Borg, 1982)

- Walking trajectory during RYSEN(AR)-training

- Training goals set by physiotherapists

- Score on fear of falling and conscious movement processing questionnaires

(Ellmers et al., 2021)

- Score on a purpose-made questionnaire about training experiences

- Score on System Usability Scale (Finstad, 2006)

Experiment D

- Input during focus group meetings

Secondary outcome

Not applicable.

Study description

Background summary

Many patients with neurological impairments, such as a stroke or spinal cord injury, show abnormal gait. This can lead to loss of indepence and mobility and may reduce quality of life. In order to increase participation, rehabilitation programs focus on improving gait.
It has frequently been shown that gait training is most effective when performed on high intensity including many repetitions of task-specific exercises. However, this is often not possible to achieve in current rehabilitation as certain levels of muscle strenght, coordination and physical fitness are thought to be required. Therefore, rehabilitation centres search for innovative solutions, such as the RYSEN, in order to organize intensive, task-specific training. The RYSEN is a 3D body weight support device that allows patients that are unable to bear their body weight to start walking early during rehabilitation. The RYSEN contains many applications that allow for task-specific training. However, currently therapisist subjectively determine the use of the RYSEN and its specific applications based on visual inspection of the gait pattern. In this project, it will be investigated how RYSEN applications can be used for specific training goals. Moreover, it will be investigated how the RYSEN contributes to rehabilitation programs in order to create specific guidelines for RYSEN use in clinical practice.

Study objective

This project has the following objectives: 1) to determine the effect of vertical, horizontal and mediolateral supportive forces of the RYSEN on gait parameters and muscle activity in able bodied individuals and patients; 2) determine the differences in training content and intensity between RYSEN(AR)-training and conventional physiotherapy; 3) determine experiences and expectations of patients and therapists regarding RYSEN-training using questionnaires and focus groups.

Study design

This project exists of four experiments (A until D), which will be executed from May 2022 until June 2025. Experiment A and B are cross-sectional studies about the effect of RYSEN-applications (vertical, horizontal and mediolateral support) on step parameters and muscle activity in healthy individuals (Experiment A) and patients (Experiment B). Experiment C will be an observational cross-sectional study in which training content, intensity and experiences will be compared between RYSEN(AR)-training and conventional physiotherapy. Experiment D will be a qualitative study that assesses training experiences and expectations in patients and therapists.

Intervention

In Experiments A & B, participants will perform experimental sessions in the RYSEN during which different RYSEN applications (vertical, horizontal and mediolateral support) will be applied. Participants will walk in the RYSEN in these different conditions and simultaneously step parameters and muscle activity will be measured.

In Experiment C, participants will perform three types of gait training within the same week; RYSEN-training, RYSENAR-training and conventional physiotherapy. Each training session will take 30 minutes and will be executed by supervision of a physiotherapist.

In Experiment D, focus groups will be organised in which experiences and expectations about RYSEN training will be assessed in patients and therapists.

Study burden and risks

Experiments A and B will have a duration of 1.5 hours. During these experiments, step parameters and muscle activity will be measured using a movement registration system (Optotrak) and electromyography.
In Experiment C, participants will perform three types of training as part of their usual rehabilitation program. Training sessions will take 30 minutes and will be supervised by a physiotherapist. During training, heart rate, acceleration of the trunk and the number of steps taken will be assessed using a heart frequency watch and inertial measurement units. After each training,

participants will be asked to fill in questionnaires, this will take about 30 minutes.
In Experiment D, participants will attend a focus group meeting for about 1.5-2 hours.

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

General inclusion criteria:
- Age >= 18 years
- Weight <= 135 kilograms
- Length <= 2 meters
- Able to provide informed consent and understand Dutch instructions

Only applicable for people after stroke:
- Suffered a first or recurrent stroke, as diagnosed by a neurologist
- Receives rehabilitation treatment care in Heliomare
- Time since stroke between 7 days and 6 months at time of inclusion (Bernhardt et al., 2017)
- Functional Ambulation Category (FAC) 2 or higher, indicating the patient is able to perform balancing and coordinating tasks with or without some assistance
- Medication that influences motor control does not alter during participation
- Received at least one RYSEN-training before participation in this study

Only applicable for people after SCI:
- Having a traumatic or non-traumatic SCI with motor incomplete (AIS C and D) as determined by ISNCSCI
- Receives rehabilitation treatment care in Heliomare
- Medication that influences motor control does not alter during participation
- Being able to stand with a standing aid
- Having MRC 3 or higher in hip muscles and quadriceps
- Received at least one RYSEN-training before participation in this study

Exclusion criteria

- Having vestibular disease
- Having visual impairments
- Having contractures or skin lesions in the lower extremities that interfere with application of the RYSEN
- Pregnancy

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-02-2023
Enrollment:	65
Type:	Actual

Medical products/devices used

Generic name:	RYSEN
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	06-02-2023
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL80828.042.22