

REWARD: REcovery of Walking Ability using a Robotic Device

Submission date 07/01/2013	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 05/02/2013	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 13/01/2015	Condition category Injury, Occupational Diseases, Poisoning	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Approximately half of the population of patients with lesions (damage) of the spinal cord have a motor or sensory incomplete lesion (iSCI), meaning that there is still some muscle function or sensory function present in regions below the lesion level. Although the majority of the iSCI population regains some form of ambulation (walking) after rehabilitation, loss of strength and coordination substantially limit the ability to walk. The improvement of walking ability is an important goal during rehabilitation after an iSCI because even small gains in ambulation can make a meaningful amelioration (improvement) of a patients daily life. In the last decade, to relieve therapists and improve duration of therapy, therapy has been automated using robotic devices such as the Lokomat, a commercially available device. The goal of this initial study is to investigate whether walking speed and other gait related outcome measures improves during an intervention in which the Lokomat device is used.

Who can participate?

Patients were recruited from both the inpatient and outpatient clinic of a rehabilitation center in Amsterdam (Reade Rehabilitation and Rheumatology, Amsterdam). Patients were asked to participate in the study if they were older than 17 years, have overall good health and have a motor or sensory incomplete lesion.

What does the study involve?

Patients were treated on the LokomatPro device (Hocoma, Switzerland) for a total of 24 sessions. Three settings were manipulated during this study: speed, amount of body weight support (BWS) and the amount of assistance of the robotic orthoses, Guidance Force (GF). These settings were used so that the patients were still able to walk for about 20-45 minutes without getting tired/exhausted. The ultimate goal was to be to walk at high but still comfortable speed, with as little body weight support and guidance force as possible for as many minutes possible within the therapy time. The duration of the training sessions was 60 minutes, including preparation time. Before and after the intervention patients had several tests to asses walking ability, strength, fitness and balance.

What are the possible benefits and risks of participating?

Patients received an extra 24 sessions therapy in the Lokomat. Possible beneficial effects are

improved walking ability, improved strength, improved fitness and improved bowel function. Information from this study will help to guide clinical recommendations on optimal therapy after incomplete spinal cord injury.

By taking part in this study these patients may become fatigued (tired) by the training. Furthermore, there is a small risk on mild burns on the skin due to friction and possible discomfort from straps with which the body weight is supported during therapy.

Where is the study run from?

The study ran from Amsterdam Rehabilitation Research Centre

When is the study starting and how long is it expected to run for?

The study started in January 2009 and has ended in late 2012.

Who is funding the study?

Funding has been provided by Revalidatiefonds

Who is the main contact?

Prof. Dr. T.W.J. Janssen

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

REWARD: REcovery of Walking Ability using a Robotic Device: a pre-test, post-test single group study

Acronym

REWARD

Study objectives

We hypothesized that patients would significantly improve their walking ability, strength and cardiorespiratory fitness during the intervention period.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Centrale Commissie Mensgebonden Onderzoek (CCMO) VU University Medical Centre (NL22052.029.08)

Study design

Pre-test post-test single group design

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Incomplete Spinal Cord Injury

Interventions

Patients are treated on the Lokomat for a total of 24 sessions, with a frequency of twice a week (for 12 weeks).

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

Walking speed at the timed 10m walk test at baseline and after the intervention of 24 sessions after twelve weeks

Key secondary outcome(s)

1. Functional Ambulation Categories (FAC)
2. Berg Balance Scale (BBS)
3. Rivermead Mobility Index (RMI)
4. Hoffer classification (HOF)
5. Self-selected Walking Index for Spinal Cord Injury II (WISCI II)
6. Timed get-up and go test (TUG)
7. Cardiorespiratory outcome measures and isometric maximal knee extension and flexion strength

Measured at baseline and after the intervention of 24 sessions after twelve weeks

Completion date

01/09/2012

Eligibility

Key inclusion criteria

Patients, both male and female were asked to participate in the study if they were older than 17 years and had a motor or sensory incomplete lesion according to American Spinal Injury Association (ASIA) classification.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Medical complications such as unstable hypertension, arrhythmias and unstable cardiovascular problems
2. Severe skeletal problems such as osteoarthritis or osteoporosis of the lower limbs

Date of first enrolment

01/01/2009

Date of final enrolment

01/09/2012

Locations

Countries of recruitment

Netherlands

Study participating centre

Van der Boechorststraat 9

Amsterdam

Netherlands

1081BT

Sponsor information

Organisation

Rehabilitation Fund (Revalidatiefonds) (Netherlands)

ROR

<https://ror.org/02vmzh064>

Funder(s)

Funder type

Government

Funder Name

Rehabilitation Fund (Revalidatiefonds) (Netherlands)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2013		Yes	No