

# REWARD: REcovery of Walking Ability using a Robotic Device

<b>Submission date</b> 07/01/2013	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/02/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 13/01/2015	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

T.W.J.Janssen@vu.nl

## Contact information

### Type(s)

Scientific

### Contact name

Prof Thomas W.J. Janssen

### Contact details

Van der Boechorststraat 9

Amsterdam

Netherlands

1081BT

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T.W.J.Janssen@vu.nl

## 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?
<a href="#">Results article</a>	results	01/06/2013		Yes	No