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REWARD: REcovery of Walking Ability using a Robotic Device

Submission date
07/01/2013

Recruitment status
No longer recruiting

Registration date
05/02/2013

Overall study status
Completed

Last Edited
13/01/2015

Condition category
Injury, Occupational Diseases, Poisoning

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
-
T.W.J.Janssen@vu.nl

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure

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

Secondary outcome measures
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

Overall study start date
01/01/2009

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

Age group
Adult

Sex
Both

Target number of participants
40

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)

Sponsor details
J.F. Kennedylaan 99
Bunnik
Netherlands
3981 GB
-
secretariaat@fbw.vu.nl

Sponsor type
Government

Website
http://www.revalidatiefonds.nl/

ROR
https://ror.org/02vmzh064

Funder(s)

Funder type
Government

Funder Name
Rehabilitation Fund (Revalidatiefonds) (Netherlands)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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