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Using the robotic gait training system (RGTS) to improve mobility functions for stroke patients

Submission date
09/12/2016

Recruitment status
No longer recruiting

Registration date
16/12/2016

Overall study status
Completed

Last Edited
15/09/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
A stroke is a serious condition where the blood supply to a part of the brain is cut off, usually by a blood clot blocking an artery (ischaemic stroke) or a bleed (haemorrhagic stroke). A large proportion of stroke victims suffer from long-term complications depending on the area of the brain that is affected, affecting their ability to speak, think and move. One of the most common complications of a stroke is paralysis (hemiplegia) or weakness (hemiparesis) on one side of the body, especially in the legs. This can make movements such as walking very difficult and so patients need extensive physiotherapy to help them recover. For several decades, traditional physical and occupational therapy programs have been used to help stroke patients learn to walk again. These recoveries are not always successful however and so it is important to find new strategies to enhance post-stroke recovery. Robotic-assisted gait training was introduced as a new treatment to improve walking recovery. It uses either an end-effector (device at the end of a robotic arm, designed to interact with the environment) or exoskeleton (external structure which supports the body underneath) to provide programmable gait (way of walking) training. This study is looking at a new Robotic Gait Training System (RGTS), which is a hybrid of end-effector and exoskeleton. The patient can receive passive stepping exercise under a weight-bearing condition. The aim of this study is to explore the feasibility and safety of this new system to find out if it is more effective than the sitting passive leg motion system (sitting and moving the leg) at helping stroke patients recover their mobility.

Who can participate?
Adults who have had a stoke 10-90 days ago which has caused substantial leg disability that is preventing them from being able to stand or walk independently.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in the first group receive treatment with RGTS for 30 minutes, once a day for 15 consecutive weekdays. This involves passive leg motion training (like stepping) while wearing the RGTS device (which holds and moves the leg). Those in the second group receive treatment with the sitting passive leg motion system for 30 minutes, once a day for 15 consecutive weekdays. This involves a passive leg

motion training (like cycling). At the start of the study and then after three weeks (end of treatment) and three months, participants in both groups have their leg function and abilities assessed.

What are the possible benefits and risks of participating?
Participants may benefit from an improvement to their leg function. There are no notable risks involved with participating.

Where is the study run from?
Shuang Ho Hospital, Taipei Medical University (Taiwan)

When is the study starting and how long is it expected to run for?
July 2015 to January 2019

Who is funding the study?
Wan Fang Hospital, Taipei Medical University (Taiwan)

Who is the main contact?
Dr Yen-Nung Lin

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N201509027

Study information

Scientific Title

In stroke patients with significant leg dysfunction, does weight-bearing passive motion exercise, compared to sitting passive motion exercise, facilitate the leg motor recovery?

Study objectives
The aim of this study is to compare the robotic gait training system (RGTS) with a sitting passive motion exercise to observe the effects on the neurological and functional levels regarding the lower extremities in stroke patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Joint Institutional Review Board of Taipei Medical University, 04/11/2015, ref: N201509027

Study design
Single-center assessor-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

Health condition(s) or problem(s) studied
Marked leg dysfunction after stroke

Interventions
The participants are randomly allocated at a 1:1 ratio to one of two study arms.

Arm 1: Participants receive treatment with the robotic gait training system. This involves a passive leg motion training (like stepping) with the RGTS device. The participant receives the training under a weight-bearing condition (ie, the legs bear weight).

Arm 2: Participants receive treatment with the sitting passive leg motion system. This involves a passive leg motion training (like cycling). With this training, the participant is under a non-weight-bearing condition (ie, the legs bear no weight).

Both interventions are delivered in daily 30 minute sessions for 15 consecutive weekdays.

Participants in both groups are followed up post-treatment and then three months later.

Intervention Type

Device

Primary outcome measure
Neurological status of legs is assessed using the lower extremity subscale of Fugl-Meyer Assessment (FMA-LE) at baseline, 3 weeks and 3 months.

Secondary outcome measures
1. Postural control is measured using the Postural Assessment Scale for Stroke at baseline, 3 weeks and 3 months
2. Body balance function is measured using the Berg Balance Scale at baseline, 3 weeks and 3 months
3. Activity of daily life is measured using the Barthel Index at baseline, 3 weeks and 3 months
4. Mobility function is measured using the Timed Up and Go test at baseline, 3 weeks and 3 months

Overall study start date
01/07/2015

Completion date
01/01/2019

Eligibility

Key inclusion criteria
1. Stroke in the past 10-90 days
2. Display substantial leg disabilities (e.g. a Brunnstrom stage (BS) of I-III in the paretic leg),
3. Unable to stand or walk independently even with orthosis included (e.g. a Functional Ambulation Classification (FAC) of 0-1)
4. Aged 18 years and over

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
60 (30 in each arm)

Total final enrolment
40

Key exclusion criteria

1. Substantial spasticity over the affected leg
2. Severe osteoarthritis,
3. Walking disabilities before the stroke

Date of first enrolment
01/01/2016

Date of final enrolment
01/09/2018

Locations

Countries of recruitment
Taiwan

Study participating centre
Shuang Ho Hospital, Taipei Medical University
No.291 Zhongzheng Road
Zhonghe District
New Taipei City
Taiwan
235

Sponsor information

Organisation
Wan Fang Hospital, Taipei Medical University

Sponsor details
111 Hsing-Long Road
Section 3
Taipei
Taiwan
116

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/058y0nn10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Wan Fang Hospital, Taipei Medical University

Results and Publications

Publication and dissemination plan
The results of this study will published on an academic journal.

Intention to publish date
01/12/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		14/09/2022	15/09/2022	Yes	No