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SWalker: a robotic platform to aid rehabilitation following hip fracture

Submission date
19/02/2021

Recruitment status
No longer recruiting

Registration date
25/02/2021

Overall study status
Completed

Last Edited
23/02/2021

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
Hip fracture is one of the most common traumas associated with falls in the elderly, severely affecting the patient's mobility and independence. The treatment involves hospitalization and prolonged rehabilitation periods with high costs which are associated with an increased mortality rate due to health complications. In recent years, the use of robotic applications has proven to be effective in gait rehabilitation, especially for neurological disorders. However, there is a lack of research in robotic rehabilitation focused on hip fracture of elderly people. This paper presents the design and validation of a novel robotic platform for hip rehabilitation called SWalker aimed at improving the rehabilitation of this condition.

Who can participate?
Patients who, after recently having undergone a hip fracture surgery, needed subsequent rehabilitation to walk again.

What does the study involve?
Participants were allocated to receive treatment using the SWalker or treatment as usual.

What are the possible benefits and risks of participating?
Benefits: The fundamental objective is to reduce patient mortality and recover the functional situation prior to hip fracture in elderly people who have suffered this pathology, and also that these achievements can be reached in the shortest possible time and at the lowest possible socio-economic cost, establishing the necessary strategies so that these benefits are maintained in the medium and long term.
Risks: No risks are foreseen.

Where is the study run from?
Albertia Servicios Sociosanitarios S.A. nursing homes (Spain)

When is the study starting and how long is it expected to run for?
March 2018 to April 2020

Who is funding the study?
1. Centro para el Desarrollo Tecnológico Industrial (CDTI) of the Ministry of Science and Innovation, Government of Spain
2. EDER/ Ministry of Science and Innovation/AEI) (Spain)

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
SWALKERS17

Study information

Scientific Title
SWalker: a robotic platform for hip fracture rehabilitation

Acronym
SWalker

Study objectives

Hip fracture is one of the most common traumas associated with falls in the elderly, severely affecting the patient's mobility and independence. The treatment involves hospitalization and prolonged rehabilitation periods with high costs which are associated with an increased mortality rate due to health complications. In recent years, the use of robotic applications has proven to be effective in gait rehabilitation, especially for neurological disorders. However, there is a lack of research in robotic rehabilitation focused on the hip fracture of elderly people. This study presents the validation of a novel robotic platform for hip rehabilitation called SWalker aimed at improving the rehabilitation of this condition in comparison with conventional rehabilitation.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 15/01/2019, Fundación Jiménez Díaz Clinical Research Ethics Committee (Avda. de los Reyes Católicos, 2, 28040-Madrid, Spain; +34 915443720; ceic@fjd.es), ref: CPMP/ICH/135/95

Study design
Interventional non-randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Recovery from hip fracture in elderly people

Interventions
The performance of the SWalker platform was assessed at Albertia Servicios Sociosanitarios S.A. nursing homes.
Clinical validation was conducted with hip fracture patients.

The control group consisted of patients who followed conventional therapy, while the intervention group consisted of patients rehabilitated using SWalker. Allocation to groups was according to the choice of the participants. All patients had the possibility to use SWalker treatment.

Physiological parameters, and functional assessment scales such as FAC and Tinetti were collected at the beginning and at the end of the intervention. Gait recovery and rehabilitation process indicators were also gathered.

The total duration of the clinical validation was 15 months.
For each patient, the total duration of treatment was between 1 week and 1 month with the robotic platform.
For those patients who received conventional rehabilitation, treatment duration was up to 6 months in the most severe case. Patient follow-up was conducted in parallel with the clinical trials.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
SWalker

Primary outcome(s)
1. Effectiveness of the device in injury recovery was measured with the variables "Number of physiotherapy sessions" and "Injury recovery time", which were quantified for each patient after the end of treatment (recovery defined as: no technical assistance or support staff needed to move around)
2. Degree of gait recovery measured by visual inspection by the clinical staff, assessing at the end of treatment whether the patient had fully recovered independent walking to perform their daily functional tasks (no technical assistance or support staff needed to move around), partially (requiring technical assistance such as a conventional walker, wheelchair, etc.) or not recovered walking at all

Key secondary outcome(s))
1. The quality of the patient's gait was measured with the Barthel index, Functional Ambulation Category (FAC), and Tinetti scale at the beginning and at the end of the treatment
2. The patients' nutritional and cognitive state was measured with the Mini Nutritional Assessment (MNA) and the Mini Examen Cognoscitivo (MEC) at the beginning and at the end of the treatment

Completion date
15/04/2020

Eligibility

Key inclusion criteria
1. Patients who, after recently having undergone a hip fracture surgery, needed subsequent rehabilitation to restore autonomous ambulation
2. Not received any other type of HF rehabilitation therapy

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment

Key exclusion criteria
Does not meet inclusion criteria

Date of first enrolment
15/01/2019

Date of final enrolment
01/11/2019

Locations

Countries of recruitment
Spain

Study participating centre
Albertia Servicios Sociosanitarios S.A.
Las Rozas De Madrid
Madrid
Spain
28222

Sponsor information

Organisation
Albertia Servicios Sociosanitarios S.A.

Funder(s)

Funder type
Government

Funder Name
Centro para el Desarrollo Tecnológico Industrial (CDTI)

Funder Name
Ministry of Science and Innovation (Government of Spain)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publically available repository (https://zenodo.org/record/4549307#.YC6fPWhKhPZ)

IPD sharing plan summary
Stored in repository