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A robot-based gait training therapy for pediatric population with Cerebral Palsy using the CPWalker robotic platform

Submission date
01/03/2017

Recruitment status
No longer recruiting

Registration date
23/03/2017

Overall study status
Completed

Last Edited
26/11/2020

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
Cerebral palsy (CP) is a term for a number of conditions that affect movement and co-ordination. It occurs when there is a problem in the parts of the brain responsible for controlling muscles. This can be due to abnormal development of the brain or damage caused before, during or after birth. CP leads to a range of symptoms, including muscle stiffness or weakness, random and uncontrolled body movements and balance and coordination problems. Problems with walking (gait) are the most common problems seen in children with CP. Robotics are being used more and more to help people who have problems with movement. The CPWalker rehabilitation platform is a robotic device made up of a walker and an exoskeleton (device worn on the outside of the body), which provides support and guidance to patients while they can experiment with walking techniques. The device can tprovide body weight support and the exoskeleton allows different control modes in order to adapt the therapy to the patient's needs. The aim of this study is to find out if therapy involving robot-based walking sessions can help children with CP to improve their gait (walking ability).

Who can participate?
Children aged 11 to 18 years who have cerebral palsy.

What does the study involve?
All the participants receive 16 robot-based walking sessions of 70 minutes each, distributed over two months with training on two non-consecutive days per week. The patients are free to also take part in other conventional rehabilitation therapies while they are taking part in the study. The first eight sessions focus mainly on general control of movement and strength training exercises, and the second eight sessions focus on increasing independence. At the start of the study and then after eight and 16 weeks, participants undergo a range of assessments to find out if their gait and wellbeing has changed.

What are the possible benefits and risks of participating?
Participants may benefit from improving their gait (walking ability) function and speed, which could improve their quality of life. There is a small risk of muscle pain and tiredness after the therapy sessions with the robot.

Where is the study run from?
Hospital Infantil Universitario Niño Jesús (Spain)

When is the study starting and how long is it expected to run for?
August 2016 to February 2017

Who is funding the study?
Ministry of Economy and Competitiveness (Spain)

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R-0032/12

Study information

Scientific Title
Assessment evolution of a defined over-ground robot-based therapy in four children with Cerebral Palsy using the CPWalker robotic platform

Study objectives
The implementation of strength and power robot-based exercises at the same time than overground walking guidance, and performing in parallel an active head-trunk control therapy, will boost the rehabilitation of children with Cerebral Palsy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local Ethical Committee of the “Hospital Infantil Universitario Niño Jesús”, 26/06/2012, ref: R-0032/12

Study design
Single-centre non-randomised study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cerebral palsy

Interventions
Four children with CP are recruited to train with a robotic platform (CPWalker) two non-consecutive days per week for eight weeks (16 total sessions). The sessions consist of a 10-15 minutes warm-up and 60 minutes of over-ground exercise with CPWalker, including 3 minutes of independent gait as a cool-down phase. The first eight sessions correspond with general motor control and strength exercises, where the robot imposed a gait trajectory tracking. Sessions 9 to 16 are related to muscle power performance through levels of AAN strategies, where self-activity was required. All children undergo assessments at baseline, after 8 weeks and after 16 weeks.

Intervention Type
Device

Primary outcome measure
Gait function is measured using 3D gait analysis at baseline, 8 and 16 weeks

Secondary outcome measures
1. Gait-speed is measured using 10-meter walking test at baseline, 8 and 16 weeks
2. Global responses involved and endurance is measured using 6-minutes walking test at baseline, 8 and 16 weeks
3. Maximum isometric strength is measured using a hand-held dynamometer
4. Selective voluntary motor control is measured using the Selective Control Assessment of Lower Extremity (SCALE) at baseline, 8 and 16 weeks
5. The changes in gross motor function are measured using the Gross Motor Function Measure (GMFM-88) dimensions D (standing) and E (walking) at baseline, 8 and 16 weeks
6. Psychological influence of fear and pain is measured using a personal kinesiophobia assessment at baseline, 8 and 16 weeks
7. Users' satisfaction is measured using the Gillette Functional Assessment Questionnaire (FAQ) at baseline, 8 and 16 weeks

Overall study start date
01/08/2016

Completion date
01/02/2017

Eligibility

Key inclusion criteria
1. Children aged 11 to 18 years suffering from spastic diplegia
2. Gross Motor Function Classification System (GMFCS) levels I to IV
3. Maximum weight 75 kg
4. Anthropometric measures of lower limbs according to the exoskeleton of CPWalker
5. Capable of understanding the proposed exercises
6. Able to signal pain or discomfort

Participant type(s)
Patient

Age group
Child

Lower age limit
11 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
4

Key exclusion criteria

1. Patients who experimented concomitant treatments 3-months prior study (e.g. orthopedic surgery or botulinum toxin)
2. Children with muscle-skeletal deformities or unhealed skin lesions in the lower limbs that could prevent the use of the exoskeleton
3. Patients with critical alterations of motor control as dystonia, choreoathetosis or ataxia
4. Aggressive or self-harming behaviors
5. Severe cognitive impairment

Date of first enrolment
20/10/2016

Date of final enrolment
20/12/2016

Locations

Countries of recruitment
Spain

Study participating centre
Hospital Infantil Universitario Niño Jesús
Av. de Menéndez Pelayo, 65
Madrid
Spain
28009

Sponsor information

Organisation
Centre for Robotics and Automation, Spanish National Research Council

Sponsor details
Ctra. Campo Real, km 0.200
La Poveda - Arganda del Rey
Madrid
Spain
28500

Sponsor type
Research council

Website
http://www.car.upm-csic.es/

ROR
https://ror.org/02gfc7t72

Funder(s)

Funder type
Government

Funder Name
Ministry of Economy and Competitiveness (Ministerio de Economía y Competitividad)

Alternative Name(s)
Ministry of Economy and Competitiveness, MINECO, MEC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Spain

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal as soon as possible.

Intention to publish date
01/06/2018

Individual participant data (IPD) sharing plan
The patient dataset is not expected to be made available to ensure the privacy of patients. The data will be held by the Analysis Movement Laboratory of the Hospital Niño Jesús (Spain) and by the Neural and Cognitive Engineering group of the Spanish Research Council.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	27/07/2018	26/11/2020	Yes	No