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Rehabilitation of neurologically impaired and spinal cord injured: exoskeleton trial

Submission date
27/06/2022

Recruitment status
No longer recruiting

Registration date
20/07/2022

Overall study status
Completed

Last Edited
15/11/2022

Condition category
Nervous System 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
Neurological impairments can be defined as diseases of the central and peripheral nervous system. These impairments can affect the brain, spinal cord, cranial nerves, peripheral nerves, nerve roots, autonomic nervous system, neuromuscular junctions, and the muscles. Due to the physical impairment and limited mobility, most individuals with neurological impairments rely on a wheelchair as their primary form of transportation. Although wheelchairs are used by individuals to participate in exercise and sports, most wheelchair use leads to a physically inactive lifestyle. Wheelchair propulsion alone may not result in an adequate amount of physical activity per day, so individuals with neurological impairments may be more susceptible to elements of physical deconditioning and several secondary health conditions, as well as increasing their risk of death. Therefore, applying the most appropriate neurological rehabilitation techniques to restore independent walking ability is a high priority across numerous impairments.
Powered exoskeletons have recently emerged as rehabilitation tools aiming to regenerate the physical capabilities of neurologically impaired individuals. Although the development of powered exoskeletons has increased in recent years, clinical research involving the devices remains limited. Existing research highlighted how powered exoskeletons can elevate cardiorespiratory (heart/lung) and biomechanical response and can enable able-bodied participants to reach a moderate-intensity level of exercise. Further research examining the effects of exoskeleton-based rehabilitation over time may be required to reach more definitive conclusions. Therefore, proceeding from the feasibility study, this trial aims to investigate the effects of a 12-week exoskeleton-based physical activity and home-based strength training intervention on various physiological, biomechanical, emotional, and quality of life parameters. Increasing the physical activity levels of individuals with neurological impairments may aid in achieving the World Health Organisation's physical activity guidelines for health. This may promote a number of health benefits and enhance quality of life by increasing cardiorespiratory fitness, muscular strength and overall physical and mental well-being, while reducing the risk of developing cardiorespiratory-related diseases and their illnesses.

Who can participate?
Patients aged 18-70 years with neurological impairments such as spinal cord injury, stroke, multiple sclerosis, acquired brain injury etc. Participants must be able to signal pain, discomfort,

or fear reliably, have functional joint mobility, have had no orthopaedic surgery or neurosurgery within the last 6 months, and have a stable cardiovascular system. Due to the requirements of the Ekso NR™ the participant's height must be between 157.5 and 188 cm and body mass must be less than 100 kg.

What does the study involve?
This study will involve a 12-week exoskeleton-based physical activity and home-based strength training intervention. Participants will complete three sessions per week; one exoskeleton walking session with The No Barriers Foundation using the Ekso NR™, lasting up to 1 hour, and two home-based strength training sessions. At baseline (week 1), mid (week 6) and post (week 12) intervention, participants will complete an assessment session. The assessment session will involve participants completing the 6-minute walk test (6MWT), where the goal is to walk as far as possible during the 6 minutes. Throughout the 6MWT a number of physiological, biomechanical and emotional parameters will be examined. Participants will wear a face mask which will be connected to the Ganshorn PowerCube® to record cardiorespiratory parameters. Participants will also wear a chest strap heart rate monitor (Polar FT2) to record heart rate, and the Borg scale (6-20) will be employed to assess the rate of perceived exertion. Shimmer 3 electromyogram (EMG) sensors (Shimmer Sensing, Dublin, Ireland) will be attached to the lower limbs to record quadriceps, hamstring and calf muscular activation, as well as lower extremity acceleration and angular velocity. A Shimmer 3 galvanic skin response (GSR)+ unit will be attached to the index and middle finger of the participant's non-dominant hand to record emotional arousal. At each timepoint participants will complete a questionnaire to assess their quality of life. Before taking part all participants will receive sufficient familiarisation with the Ekso NR™, and their functional mobility will be assessed by a qualified and registered chartered physiotherapist from The No Barriers Foundation using a specific exoskeleton screening protocol. This functional mobility assessment will also be repeated at mid and after the intervention and referred to as a control measurement.

What are the possible benefits and risks of participating?
This study will enable the researchers and clinicians to determine the effects of exoskeleton gait training on cardiorespiratory fitness, lower limb muscle activity and movement, galvanic skin response, quality of life and mobility. The outcomes may inform future programming for exoskeleton-based rehabilitation and may enable clinicians to determine the best amount of exercise (frequency, duration, and intensity) to prescribe to individuals with neurological impairments to elicit maximal favourable adaptations in response to training. This study may provide a solid foundation for future research involving the exoskeleton, with the goal of improving overall health and wellbeing. This project will also inform the research team of the demands of exoskeleton-based rehabilitation within a neurologically impaired population and may provide exercise guidelines/recommendations for exoskeleton training. A risk assessment has been conducted to ensure participant safety.

Where is the study run from?
1. Atlantic Technological University (Ireland)
2. The No Barriers Foundations (Ireland)

When is the study starting and how long is it expected to run for?
November 2021 to November 2022

Who is funding the study?
Atlantic Technological University (Ireland)

Who is the main contact?
Mr Damien Duddy, L00126229@atu.ie

Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Physiological, biomechanical, and emotional responses to a 12-week exoskeleton-based physical activity and home-based strength training intervention among individuals with neurological impairments

Acronym
RISE

Study objectives
To conduct a quasi-experimental study to examine the effects of a 12-week exoskeleton-based physical activity and home-based strength training intervention on a range of physiological, biomechanical, emotional and quality of life parameters.

It is hypothesised that the intervention will increase the physical activity levels of neurologically impaired participants. In turn, this will promote favourable physiological, biomechanical, emotional and quality of life adaptations. Additionally, exoskeleton-based physical activity may help individuals with neurological impairments achieve the World Health Organisations' physical activity guidelines for health.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/06/2022, Atlantic Technological University Institute Research Ethics Committee (Port Road, Letterkenny, F92 FC93, Co. Donegal, Ireland; +353 (0)74 9186074; researchoffice@lyit.ie), ref: not applicable

Study design
Quasi-experimental non-randomized controlled trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Community

Study type(s)
Quality of life

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

Health condition(s) or problem(s) studied
Rehabilitation of individuals with neurological impairments

Interventions
Individuals with neurological impairments will complete a 12-week exoskeleton-based physical activity and home-based strength training intervention. Participants will complete three sessions per week; one exoskeleton-based walking session with The No Barriers Foundation lasting up to 1 hour, and two home-based strength training sessions. The Ekso NR™ is the exoskeleton that will be used throughout the intervention. It is a full lower limb powered exoskeleton that enables individuals with little to no gait function to walk overground by generating a reciprocal gait pattern. The Ekso NR™ provides full external body mass support and has motors attached at the hip and knee joints in order to generate steps. The Ekso NR™ was developed by Ekso Bionics® (Richmond, CA, USA) and is owned by "The No Barriers Foundation". The sessions will

be prescribed based on the World Health Organisation's physical activity guidelines for health for adults living with disability, the American College of Sports Medicine strength training guidelines and individual capabilities. Participants will start by doing small amounts of physical activity i.e., exoskeleton walking, and increase the frequency, intensity and duration over time aiming to adhere to the recommended guidelines of 150-300 minutes of moderate-intensity activity or 75-150 minutes of vigorous-intensity activity, or an equivalent combination of both per week. The strength training sessions will consist of 8-10 multi-joint exercises and 2-3 sets of 8-12 repetitions with good technique will be performed per exercise. The sessions will be progressively overloaded to continually challenge participants.

An assessment session will be conducted at baseline (week 1), mid (week 6) and post (week 12) intervention, which will involve all participants completing the 6-minute walk test (6MWT). The aim of the 6MWT is to walk as far as possible along a flat surface (15m) within the 6-minute timeframe. Gait performance parameters such as total walking distance and walking speed will be calculated.

Prior to the intervention commencing, all participants will receive sufficient familiarisation with The Ekso NR™. A qualified and registered chartered physiotherapist from The No Barriers Foundation will assess participants' functional mobility using a specific exoskeleton protocol. The functional mobility screening will repeated by the physiotherapist at mid and post intervention to identify any improvements.

Throughout the 6MWT physiological, biomechanical and emotional responses will be recorded. Physiological responses will be recorded by the Ganshorn Ganshorn PowerCube® (Ganshorn, Niederlauer, Germany), which will generate a range of measurements, such as volume of oxygen consumption per kilogram (kg) of body mass (VO2kg–1), volume of carbon dioxide per kg of body mass (VCO2kg–1), respiratory exchange ratio (RER), ventilation (VE) and metabolic equivalents (METs), which will be recorded every minute during the 6MWT.

Additional physiological parameters such as heart rate (HR) will be recorded every 30 seconds using a Polar FT2 (GEN 90037558, Electro, Finland) chest strap HR monitor, and rate of perceived exertion (RPE) will be measured during the last 15 seconds of each minute using the Borg Scale (6-20 scale).

Biomechanical response will be measured using Shimmer 3 electromyogram (EMG) sensors (Shimmer Sensing, Dublin, Ireland). Throughout the 6MWT the sensors will record muscle activation of the vastus lateralis, rectus femoris, biceps femoris, semitendinosus, medial gastrocnemius head and soleus on both legs (sampling rate 512 Hz). The built in inertial measurement unit will be employed to record lower extremity acceleration and angular velocity.

Throughout the 6MWT emotional response will be assessed using a Shimmer 3 galvanic skin response (GSR)+ unit (Shimmer Sensing, Dublin, Ireland). The GSR unit will be attached to the index and middle finger of the participants non-dominant hand and will measure changes in skin conductivity which will indicate emotional arousal.

At each assessment timepoint participants will also complete the EQ-5D-5L questionnaire developed by EuroQol (Rotterdam, The Netherlands) to assess quality of life.

Intervention Type
Behavioural

Primary outcome measure

The physiological response to the intervention, measured using:
1. A range of cardiorespiratory measurements generated by the Ganshorn PowerCube®
2. HR recorded using a Polar FT2 (GEN 90037558, Electro, Finland) chest strap HR monitor
3. RPE measured using the Borg Scale (6-20 scale)
These measurements will be recorded throughout the 6MWT, which will be conducted at baseline, mid, and post-intervention.

Secondary outcome measures
1. Gait function is measured using the 6MWT which includes total walking distance and walking speed and will be recorded at baseline, mid, and post intervention
2. Functional mobility will be measured by a qualified and registered chartered physiotherapist using specific exoskeleton protocols at baseline, mid, and post intervention
3. Biomechanical response will be measured using Shimmer 3 EMG sensors, which will record lower limb muscle activation, acceleration and angular velocity throughout the 6MWT at baseline, mid, and post intervention
4. Emotional response will be measured using a Shimmer 3 GSR+ unit during the 6MWT at baseline, mid, and post intervention
5. Quality of life will be measured using the EQ-5D-5L quality of life questionnaire developed by EuroQol at baseline, mid, and post intervention

Overall study start date
16/11/2021

Completion date
11/11/2022

Eligibility

Key inclusion criteria
1. Adults with a neurological impairment (e.g., spinal cord injury, multiple sclerosis, acquired brain injury, stroke)
2. Aged 18-70 years old
3. Height: ≥157.5 and ≤188 cm and body mass: ≤100 kg
4. Able to signal pain, discomfort, or fear reliably
5. Functional joint mobility (ankle dorsiflexion = neutral; knee flexion = 0–120°; hip flexion = 0–90°; and hip extension = 0–10°)
6. No orthopaedic surgery or neurosurgery within 6 months prior
7. A stable cardiovascular system

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
12

Total final enrolment
6

Key exclusion criteria
1. Contractures, fractures or joint dislocations in the lower extremities
2. Osteoporosis
3. Height: <157.5 and >188 cm and body mass >100 kg
4. Unequal leg length
5. Unhealed skin lesions in the lower limbs
6. Thromboembolic diseases or cardiovascular instability

Date of first enrolment
07/06/2022

Date of final enrolment
09/08/2022

Locations

Countries of recruitment
Ireland

Study participating centre
Atlantic Technological University
Port Road
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Study participating centre
The No Barriers Foundation
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Sponsor type
University/education

Website
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Funder(s)

Funder type
University/education

Funder Name
Atlantic Technological University

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal and presentations at relevant conferences.

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan
The 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