ISRCTN92095509 https://doi.org/10.1186/ISRCTN92095509

Does the use of a robotic rehabilitation trainer change quality of life, range of movement and function in children with cerebral palsy?

Submission date
02/02/2022

Recruitment status
No longer recruiting

Registration date
16/03/2022

Overall study status
Completed

Last Edited
22/12/2022

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Current recommendations suggest that all children should access participate in about 60 minutes of moderate to vigorous exercise per day to improve overall health and quality of life. This includes children with a disability such as cerebral palsy (CP), which is the most common physical disability in childhood, occurring in 1 in 500 live births. However, moderate to vigorous exercise is particularly challenging in children with CP classified as Gross Motor Function Classification System (GMFCS) level IV or V, who are unable to walk or stand without aid or equipment. As a result, children with CP (GMFCS levels IV or V) are more likely to be predominantly sedentary (inactive), leading to negative health outcomes.
Robot-assisted therapies, such as the Innowalk Pro (IP), have evolved over the last 15 years and are increasing equity of access to therapy since they include adjustable settings to account for differences in range of movement, tone, and functional ability. Emerging evidence suggests improvements in quality of life from using robot-assisted devices, reported by both parents and patients. A robotic rehabilitation trainer (RRT) allows patients with severe physical disability to stand and move in an upright position with natural weight-bearing. It provides assisted, guided, and repetitive movements, giving the user flexibility in adjustment and support, allowing for mobilisation with high intensity. The aim of this study is to explore the effects of the Innowalk on quality of life, as reported by parents.

Who can participate?
Students who attend a special school in London, aged 5-18 years, with cerebral palsy and who are unable to stand or walk unaided

What does the study involve?
All participants in the study will receive their usual level of physiotherapy care before during and after the trial is completed, this includes the use of standing frames/walkers/direct physiotherapy sessions as needed, and this will not change due to them being involved in the study.
Participants' quality of life is assessed up to 5 days before they start using the RRT. The students will be assessed before the trial begins to assess the set up for each child which will be carried

out by the physiotherapist, this requires measurements of the length of knee crease to the sole of the foot, and the height of the student to be taken. Measurements are taken on the day of the trial before the participants begin using the RRT by a trained member of the research team. Each participant will receive the intervention of using the RRT for 30 minutes a day, 4 times a week for 6 weeks. The RRT has a tablet which will record the time each participant has spent using the equipment, what angle they stood at, how far they technically travelled in metres and the participants' satisfaction when using it using a four-point scale of smiley faces – sad, indifferent, happy and very happy. This is recorded at the end of every session the participant has using the equipment. If the desired 30 minutes using the RRT is not reached for a reason this will be recorded.
On the final day of using the RRT, within an hour after completing the session of 30 minutes; all measurements will be repeated by a physiotherapist within 1 hour. Quality of life will also be assessed again within 2 days of the participants completing the intervention.
All assessments will then be repeated 6 weeks and 3 months following the completion of the intervention. Once the intervention is completed there will be no change in the provision of physiotherapy within the school to what they normally receive and therefore they will receive their usual standard of care.

What are the possible benefits and risks of participating?
The intervention of using the Innowalk Pro is not perceived to involve higher risk than what is known from their usual physiotherapy treatment as it offers movement through their available range of movement of their lower limbs.
It is important to note that although there have been no reports of this to the researchers' knowledge, if a child has a diagnosis of brittle bones or low bone density there is a potential risk of fracture. This is only a precaution, and each child will be closely monitored throughout the study.
Another risk is a potential for friction/pressure areas around areas of contact on the Innowalk, for example the shins and feet. This will be checked regularly to try and minimise risk.
There is a risk that any child may experience some pain or discomfort using the Innowalk. This will be monitored for very closely and if there are any signs of pain or discomfort, the use of it will be stopped immediately and reviewed by a physiotherapist. If once it has been reviewed by the physiotherapist and the child continues to experience pain or discomfort, they will cease to continue with the trial. If this is the case data will still be collected up until that point.
Smaller studies have shown some positive effects of using the Innowalk, such as improved range of movement, but this cannot be generalised to every child.
By consenting to participate in this study means each child will have access to the Innowalk Pro which will allow them to experience movement and time out of their chair for 30 minutes more than their usual postural program four times a week for 6 weeks.
Each child taking part in the study will be adding to evidence around the best use of the Innowalk. If benefits are evidenced through the research, these benefits are likely to also be experienced by other children with cerebral palsy as a consequence of its discovery.

Where is the study run from?
Whittington Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?
August 2018 to October 2021

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Clare Grodon
clare.grodon@nhs.net

Contact information

Type(s)
Principal investigator

Contact name
Miss Clare Grodon

Contact details
Richard Cloudesley Senior School
Tudor Rose Building
1 Prebend St
London
United Kingdom
N1 8RE
+44 (0)2032270602
clare.grodon@nhs.net

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
260371

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 260371, CPMS 43403

Study information

Scientific Title
A prospective, single-arm, pre-post trial to investigate whether quality of life, range of movement (ROM), spasticity and function, in children with cerebral palsy (GMFCS IV-V) can be affected using a robotic rehabilitation trainer for 30 minutes, 4 times a week for 6 weeks

Acronym
heROIC

Study objectives

The primary research question is to assess the effect of the Innowalk Pro in a special school setting on the quality of life (QOL) of children with cerebral palsy (CP) (Gross Motor Function Classification System [GMFCS] IV-V), to address the hypothesis that the Innowalk Pro will improve QOL over a 6-week period of being used 4x a week for 30 minutes. Secondary objectives will assess the effect of the Innowalk Pro over a 6-week period on range of movement and spasticity in the lower limbs as well as patient-specific goals and whether any effects are sustained at 6 weeks and at 3 months after the intervention has stopped.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 13/01/2020, London - Camden and Kings Cross Research Ethics Committee (Health Research Authority, NHSBT Newcastle Blood Donor Centre, Holland Drive, HRA Newcastle, NE2 4NQ, UK; +44 (0)207 104 8277; camdenandkingscross.rec@hra.nhs.uk), REC ref: 19/LO/1721

Study design
Single-centre single-arm pre-post study

Primary study design
Interventional

Study type(s)
Quality of life

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

Interventions
This trial will not use randomisation due to it being a single-arm pre-post intervention using a convenience sample. All participants in the study will receive their usual level of physiotherapy care before during and after the trial is completed, this includes the use of standing frames /walkers/direct physiotherapy sessions as needed, and this will not change due to them being involved in the study.
The Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD) and Goal Attainment Scale (GAS) data will be taken up to 5 days before the intervention of using the robotic rehabilitation trainer (RRT) starts. The students will be assessed before the trial begins to assess the set up for each child which will be carried out by the physiotherapist, this requires measurements of the length of knee crease to the sole of the foot, and the height of the student to be taken. The measurement of the popliteal angle, hip and knee extension, dorsiflexion with knee extended and knee flexed, and spasticity of the rectus femoris, hamstrings, gastrocnemius and soleus will all happen on the day of the trial before the participants begin using the RRT. All measurements will be taken by a trained member of the research team.

Each participant will receive the intervention of using the RRT for 30 minutes a day, 4 times a week for 6 weeks. The RRT has a tablet which will record the time each participant has spent using the equipment, what angle they stood at, how far they technically travelled in metres and the participants' satisfaction when using it using a four-point scale of smiley faces – sad, indifferent, happy and very happy. This is recorded at the end of every session the participant

has using the equipment. If the desired 30 minutes using the RRT is not reached for a reason this will be recorded.

On the final day of using the RRT, within an hour after completing the session of 30 minutes; all measurements of the popliteal angle, hip and knee extension, dorsiflexion with knee extended and knee flexed, and spasticity of the rectus femoris, hamstrings, gastrocnemius and soleus will be repeated by a physiotherapist within 1 hour. The CPCHILD and GAS data will also be re-collected from parents within 2 days of the participants completing the intervention.

All outcome measure data will be re-collected at 6 weeks following the last day of intervention (+/-3 days) and again at 3 months (+/- 3days). All range of movement (ROM) measurements of the popliteal angle, hip and knee extension, dorsiflexion with knee extended and knee flexed, and spasticity of the rectus femoris, hamstrings, gastrocnemius and soleus will be repeated by a physiotherapist in school. The CPCHILD and GAS data will also be re-collected from parents again at this time. The CPCHILD data is collected via a questionnaire which is intended to be self-administered. They can complete it at home and send it back via their child to school or complete it at the school if they prefer. If the questionnaires are not sent back within 5 days of it being sent out, then the Physiotherapist will call the parents to ask for the information over the phone. The collection of data from the GAS goals should be completed by the physiotherapist in conjunction with speaking to the parents and therefore establishing if they have met their goal set prior to the intervention taking place.

Once the intervention is completed there will be no change in the provision of physiotherapy within school to what they normally receive and therefore they will receive their usual standard of care.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Innowalk Pro

Primary outcome(s)
Quality of life (QOL) measured using the CPCHILD questionnaire for parents and caregivers, before (-3/5 days) the intervention starts, immediately when the intervention ends after 6 weeks, and repeated 6 weeks and 3 months following the completion of using the Innowalk pro

Key secondary outcome(s))
1. Range of movement of hip extension, ankle dorsiflexion with knee extended and flexed, knee extension measured using a goniometer, immediately pre and post the intervention period of 6 weeks and repeated at 6 weeks and 3 months on completion of using the Innowalk Pro
2. Popliteal angle measured using a goniometer immediately pre and post the intervention period of 6 weeks and repeated at 6 weeks and 3 months on completion of using the Innowalk Pro
3. Hamstring, soleus, gastrocnemius and rectus femoris spasticity measured using the Modifed Tardieu Scale immediately pre and post the intervention period of 6 weeks and repeated at 6 weeks and 3 months on completion of using the Innowalk Pro
4. Perceived function measured using Goal Attainment Scale, before (-3/5 days) the intervention

starts, immediately when the intervention ends after 6 weeks, and repeated at 6 weeks and 3 months following the completion of using the Innowalk pro

Completion date
15/10/2021

Eligibility

Key inclusion criteria
1. Children aged 5-18 years
2. Attends the special school (primary and secondary)
3. Diagnosis of CP classified at level IV-V
4. Parents/legal guardians give consent to partake in the trial

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
18 years

Sex
All

Total final enrolment
27

Key exclusion criteria
1. Any child who has had orthopaedic surgery in the last year to their lower limbs
2. Any child who meets the criteria but has had botox in their lower limbs within 3 months of the trial
3. Any child who meets the criteria however is younger than 5 or older than 18 years
4. Any contractures that don't allow access to the Innowalk Pro
5. Any orthopaedic/medical advice not to stand
6. Fixed flexion deformity of the hip >40 degrees, knee >50 degrees
7. Severe scoliosis, windswept deformity, contractures or other deformities interfering with the positioning of a user in the Innowalk Pro
8. Epilepsy not controlled by medication
9. Lack of head control which is not possible to support in the Innowalk Pro
10. Skin lesion/pressure areas in the contract areas of the padding/contact with the device
11. Osteoporosis with previous or suspected spontaneous fractures of the lower extremities
12. Lack of compliance of acceptance of dynamic standing

13. Intolerance, pain or not able to cooperate or be positioned adequately within the Innowalk Pro

Date of first enrolment
10/02/2020

Date of final enrolment
07/06/2021

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Whittington Health NHS Trust
The Whittington Hospital
Magdala Avenue
London
United Kingdom
N19 5NF

Sponsor information

Organisation
Whittington Health NHS Trust

ROR
https://ror.org/02vg92y09

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

Any requests for participant-level data are to be made to the Chief Investigator Clare Grodon (clare.grodon@nhs.net) at Whittington Health. There will be an electronic case report form (eCRF) to record individual patient data that can be provided. The eCRF is stored on an Excel spreadsheet so it can be easily read and understood with any coding clearly explained. It will have no identifiable information so data protection is maintained and participant consent is not required. This data is stored on the Whittington Health NHS secure database which only members of the research team will be able to access on Whittington Health NHS computers via a personal login with a username and password. The data will be available for a period of 2 years. Direct access will be granted to authorised representatives from the Sponsor, and the regulatory authorities to permit trial-related monitoring, audits and inspections in line with participant consent. Any other requests will be assessed on a case by case basis by the Chief Investigator with support from the Sponsor if required. All records of participants, original case record forms, signed informed consent forms, consultee declaration forms, and hospital records will be stored securely under the supervision of the Chief Investigator and separate from the eCRF to ensure patient confidentiality as they contain personal and identifiable data. Patient confidentiality will be maintained throughout the trial and on the publication of the research. All investigators and trial site staff will comply with the requirements of the Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles.
Trial results will be disseminated to participants and their parents/legal guardians on completion of the final trial report via a summarised report. Parents/legal guardians can request data for their child at any time during the trial. Participant-level data that is provided will be checked prior to ensure no identifiable data is included.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		21/12/2022	22/12/2022	No	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Child version 1.1	18/12/2019	09/02/2022	No	Yes
Participant information sheet	Parent version 1.1	18/12/2019	09/02/2022	No	Yes
Participant information sheet	Participant information sheet version 1.1	11/11/2025	11/11/2025	No	Yes
Protocol file		18/12/2019	17/08/2022	No	No