Parent Participant Information Sheet

Study Title: The heROIC trial : Does t**he** use of a robotic rehabilitation trainer (**R**RT) improve Q**O**L, ROM & functional goals **i**n children with **C**P?

Introduction
We'd like to invite your child to take part in our research study. Your child joining the study is entirely up to you, before you decide we would like you to understand why the research is being done and what it would involve for you and your child. One of our team will go through this information sheet with you, to help you decide whether or not you would like your child to take part and answer any questions you may have. We'd suggest this should take about 30 minutes. Please feel free to talk to others about the study if you wish.

What is the purpose of the study?

To investigate whether using the Innowalk Pro in school for 30 minutes a day for 4 days a week over a 6 week period affects quality of life and whether any effects last over a 6 week or 3 month period.
The Innowalk Pro is a robotic rehabilitation trainer (RRT) offering the possibility for assisted repetitive walking movements close to normal gait in an upright weight-bearing position. This movement generates flexion and extension of the hip, knee and ankle joints in a fully supported position.

Why has your child been invited? The research is investigating whether use of the Innowalk pro in children with a diagnosis of cerebral palsy GMFCS IV/V (meaning they use a wheelchair for the majority of their mobility) is beneficial.

What does taking part involve?

Before you and your child decide to take part in the study, you need to be aware of everything involved.

Screening and exclusion

- As the school physiotherapist and chief investigator of the study, your child's medical records are accessible to the physiotherapist and therefore it is known that they are eligible for this trial.
- The physiotherapist (Chief Investigator) needs to know whether your child has had botulinum toxin injections in the last 3 months or is having any planned botulinum toxin in the next 3 months in their legs as this will mean they are not eligible to take part in the study within that timeframe but may be eligible after this timeframe.
- The Physiotherapist (Chief Investigator) needs to know whether your child has had surgery (not known to them already) or has any planned surgery over the duration of the trial as they will not then be eligible for the study.

What tests will be involved?

- All assessments will be carried out by the physiotherapy team, in school but out of the classroom, these are mostly used in normal practice and will take about 20minutes. They will be repeated four times (pre-intervention, immediately post-intervention, 6 weeks following the end of the intervention phase and 3 months following the end of the intervention phase) and includes:

  - Range of movement assessments for knee and hip extension and ankle dorsiflexion.

  - Assessment of lower limb muscles for spasticity. (Hamstrings, Rectus Femoris, Soleus and Gastrocnemius)

  -Quality of Life assessment questionnaire to be carried out by parents.

  - Setting of joint goals between the physiotherapist and the parents/guardians.

- There is no invasive screening to take place and therefore very low likelihood of discovering any significant health related findings.

Research activities

- If you give consent for your child to take part in the study they will continue to receive their standard level of physiotherapy input, including the use of their standing frame (if applicable), walker (if applicable) routine stretches, PE sessions and hydrotherapy (if applicable). In addition to this routine physiotherapy they will participate in 30 mins of using the Innowalk Pro for 4x a week for 6 weeks.
- If you consent, you are consenting to the assessments mentioned above being carried out and for the collection of data to be analysed
- Please note that by consenting for your child to take part in the study, data from your child's medical records will be used for data analysis purposes. This will include their GMFCS level, whether they have had recent botulinum toxin injections, and any recent surgery. There will be no identifiable information from their medical records used in the trial or published at any time.
- All assessments (other than the quality of life questionnaire and goal setting assessment) will be completed in school.

- Assessment for the Innowalk Pro will be carried out by the Physiotherapist and then trained Teaching assistants (TA's), will support your child to use the equipment for the 30 minutes a day 4 days a week alongside their usual routine. A device on the equipment records how long they use it each day, how fast they go in it, how far they travel, what degree of standing they achieve, and how much your child enjoyed the experience.
- Your child will be hoisted on and off the equipment, fully supported in the equipment by the chest and leg supports and supervised at all times during the process.
- Once the 6 week block of using the Innowalk Pro is complete, they will return back to receiving their usual level of physiotherapy input, but will not have access to the Innowalk Pro again until after their involvement in the trial has ended, which is when all assessments have been completed 3 months following the last day they used the equipment. This is because if they use the Innowalk Pro after the intervention phase has ended it could alter the results from longer term follow-up.
- For the participants involved in the study using the Innowalk Pro for 30 minutes will become a normal part of their routine and blend into their standard clinical care over the 6 week period of the intervention phase, and happen in the classroom setting so as not to miss out on any other aspect of their education. All other aspects of their physiotherapy care will remain the same.
- The study does not plan to involve any videoing or photography for the purposes of the trial.

Do I have to take part?

No, it is up to you to decide whether your child takes part in the study. If you do decide for your child to take part you are free at any point to withdraw them without giving a reason, although you may be asked by the research team. Not-participating in this research or consenting and later withdrawing will not affect the care or treatment that your child is entitled to in any way.

What are the possible benefits of taking part?

- It is not possible to promise any direct benefits of your child taking part in the research as we are not yet aware of many of the outcomes which is why we are conducting the research. Smaller studies have shown some positive effects of using the innowalk, such as improved range of movement, however this cannot be generalised to every child.
- By consenting for your child to participate in this study means they 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 4x a week for 6 weeks.
- By consenting for your child to take part in the study, they will be adding to evidence around the best use of the Innowalk and potentially contribute towards creating a protocol into how it should be used for the children not only in Richard Cloudesley school but potentially across other school settings if successful.
- By consenting for your child to participate in the study, 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.

What are the possible disadvantages and risks of taking part?

There are no known disadvantages to using the innowalk pro if they are assessed for it correctly and setup is carried out according to the manual and initially done by a physiotherapist.

It is important to note that although there have been no reports of this to our knowledge, if your child has a diagnosis of brittle bones or low bone density, there is a potential risk of fracture. This is only a precaution, and your child will be closely monitored throughout the study.

Another risk to note is that there 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 risk that your 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 your 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.

Whittington Health cover patient indemnity insurance for any treatment provided and Made for Movement have their own public and product liability insurance for the equipment itself if there is any breakdown or problems with the Innowalk Pro.

It must be noted that there is a very small risk of identifiable information being accidentally disclosed however precautionary measures will be put in place to minimise this risk as much as possible. Any identifiable information will be kept separate from any data collected from the study and all information will be safely stored in a locked cabinet of which only the investigators have access to. Data that is saved on a computer is encrypted according to NHS information governance regulations. As all members of the research team have access to identifiable information they will continue to work within their professional remit to ensure confidentiality is maintained throughout the study.

If during the course of the study auditors, inspectors or monitors need to access information about the study they will not have any access to identifiable information.

The principal investigator is intending to work with external sources to support with statistics for the results of the study as well as for publication of the study. When information is shared at this time participant confidentiality will be maintained as any identifiable information will have been kept separate from the data collected and therefore each participant's data will be coded for the purpose of the investigator, and external sources will not have access to this code, only to the data itself. The only information that will be published will be the GMFCS level of the participant, their baseline data and any data collected as a part of the study which has been previously explained.

Any data collected for research purposes must be stored for 25 years. This will be done electronically through the NHS secure system through Whittington Health. No identifiable information will be kept in this file.

All records that are identifiable will be kept in your child's medical records, and notes will be written as normal according to HCPC standards, with any assessments they have carried out as a part of

the research recorded appropriately. This information can be shared with relevant medical professionals and parents/legal guardians only.

Once the data is analysed appropriately, results can be shared and the full research paper can be submitted to relevant journals, to be peer reviewed before it is published. Participant confidentiality will continue to be maintained as no identifiable information will be published in this journal. It is important that the research is disseminated appropriately at this time to ensure knowledge can be shared about the use of the innowalk especially within a school setting.

Psychological risk

The quality of life questionnaire which will be used as a part of this research is to be filled out by yourselves as parents/legal guardians of the participants in the study. The questionnaire might raise some questions which you may find difficult/challenging to answer. If you feel you need extra support due to the questions raised please let either the principal investigator or a member of the health/therapy team know who can direct you to relevant support if needed.

Will my taking part in the project be kept confidential?

Confidentiality break statement: The information you provide will be accessed only by members of the research team, for the purpose of this study, and will not be shared with any other parties. The only exception to this would be any information you give us which indicates that you, your child or somebody else, is at risk of harm **or** if there has been an incidence of negligence or malpractice on behalf of the research team. In this case we would need to adhere to local Whittington Health procedures which follow the duty of care to safeguard your child meaning we may need to pass on information you have given us to the applicable authorities such as social services, GP or the police. If you give consent we will let your child's GP know that your child is taking part in the study.

What will happen to my information?

Your rights to access change or move your information are limited, as we need to manage your child's information in specific ways in order for the research to be reliable and accurate. If you withdraw your child from the study, we will keep the information about your child that we have already obtained. To safeguard you and your child's rights, we will use the minimum personally-identifiable information possible. If you would like any more information about how we store data please speak to a member of the research team.

What will happen to the results of the project?

The intention for this dissemination of the research is that it will be published in relevant paediatric papers, and will be presented at relevant Physiotherapy/cerebral palsy conferences. A summary of the research findings will be sent to all participants parents automatically, unless you request for this not to be.

Who is organising and funding this project?

Whittington Health is the Sponsor for this study and NoClor is the Research & Development Office for Whittington Health, a collaborator that is organizing this research, these organisations are based in the United Kingdom. Whittington Health and NoClor will be using information from the participant and their medical records in order to undertake this study. Whittington Health will act as the data controller for this study, this means that we are responsible for looking after your information and using it properly. Whittington Health will keep identifiable information about the participant for no longer than 25 years after the study has finished.

Who has reviewed the project?
All research that takes place within the NHS is looked at by an independent group called the National Research Ethics Committee, to protect your interests. This study has been reviewed and given Favourable Opinion by the London-Camden and Kings Cross Research Ethics Committee.

What if I have concerns or there is a problem?
If you have any concerns about any aspect of this research please speak to a member of the research team in the first instance who will do their best to address the issue. If you remain unhappy and wish to complain formally you can do this by contacting Whittington Health PALS via email whh-tr.whitthealthPALS@nhs.net or calling 02072885551.

What if something goes wrong?
In the event that something does go wrong and your child is harmed during the research and this is due to how the research has been designed or someone's negligence then you may have grounds for legal action for compensation against Whittington health NHS trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you via PALS.

How to contact the research team

Trial Coordinator/Manager
Clare Dorset-Purkis
Paediatric Physiotherapist
clare.dorset-purkis@nhs.net
02077864804
Richard Cloudesley School Primary
101 Whitecross Street,
London
EC1Y 8JA

You will be given a copy of the information sheet and a signed consent form to keep.

- *Thank you for considering taking part or taking time to read this sheet.*

This information document explains how health researchers use information from patients. If you are asked to take part in research, you can ask what will happen in the study.

How will we use information about your child?

We will need to use information from your child's medical records for this research project.

This information will include your child's name/NHS number. People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who your child is will not be able to see their name or contact details. Their data will have a code number instead.

We will keep all information about you/your child safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

What are your choices about how your information is used?

- Your child can stop being part of the study at any time, without giving a reason, but we will keep information about them that we already have.
- If you choose for your child to stop taking part in the study, we would like to continue collecting information about your health from NHS records. If you do not want this to happen, tell us and we will stop.
- We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

The DPO for **Whittington Health NHS Trust** can be contacted via email at InformationGovernance.Whitthealth@nhs.net or by calling 0207 288 3077.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to clare.dorset-purkis@nhs.net
- by ringing us on 02077864804.