Torbay Medical Research Fund

The RAINCOAT study:
EVERYDAY WALKING IN CROUCH GAIT in
children with cerebral Palsy

UNIVERSITY OF
PLYMOUTH

## Parent/Guardian Information Sheet for Child to Participate

**V4: 19/05/22**

## The RAINCOAT Study: EVERYDAY WALKING IN CROUCH GAIT in children with cerebral palsy

### RESEARCH title: How does selective motor control and knee extensor strength impact on crouch gait in children with cerebral palsy during an everyday walking circuit?

We would like to invite your child to take part in our research study. Before you and your child decide whether to take part, we would like you to understand why the research is being done and what it will involve. One of our team will go through this information with you and answer any questions you may have. Take time to decide whether you want to take part and talk to other people about the study if you wish.

The main researcher is Harriet Hughes, a physiotherapist who is highly experienced in working with children and young people with cerebral palsy. She is doing this study as part of her PhD and her supervisory team is Prof John Marsden (University of Plymouth) and Dr Cherry Kilbride (Brunel University, London).

### What is the purpose of the study?

The purpose of this study is to learn more about crouch gait during everyday walking. Crouch gait is one of the most common walking problems affecting children and young people with bilateral cerebral palsy. Crouch gait is a tiring walking pattern, characterized by excessive knee bend when walking and if left untreated may lead to chronic knee pain and difficulty with walking. The cause of crouch gait is unclear, with potential factors including, knee muscle weakness, knee muscle tightness and difficulties moving joints independently of one another.

In this study we want to find out how factors such as knee muscle strength impact on crouch gait during everyday walking activities where children and young people encounter, slopes and steps. It is hoped that this will enable the development of new treatment approaches for young people with cerebral palsy and crouch gait, which target real-life difficulties they may experience daily, when walking outside.

### Why has my child been chosen?

Your child has been chosen because they are aged between 6-18 years old and have cerebral palsy. Before your child can begin the study, we will need to ask you some questions to see if they are eligible to participate. Some young people with cerebral palsy won’t be able to take part, if for example, they are unable to walk up and down steps or slopes with a rail.

### Does my child have to take part?

No. It is up to you and your child, whether to participate or not. Before you decide, a member of the research team will explain the study and go through this information sheet with you. If you decide to take part and are over 16 years old, we will ask you to sign a consent form allowing participation.

You will be given a copy of the information sheet and the signed consent forms to keep for your records. You and your child are free to withdraw at any time, without giving a reason. This will not affect the standard of care your child receives in the future.

**What will my child have to do if we choose to take part?**

If you and your child decide to take part the researcher will arrange a convenient time to discuss the study over the phone or via a video call (according to your preference) and to screen whether your child is eligible to participate in the study. If you and your child then decide to participate in the study the researcher will invite you for a one-off study assessment at the University of Plymouth, Human Movement and Function Lab, based in the School of Allied Health Professions.

During this assessment, the researcher will measure your child's knee muscle strength and stiffness using a device called a Dynamometer (See figure 1). This will involve pushing or pulling against a strap placed around their leg and having the leg moved at different speeds by the dynamometer. None of these leg measurements will hurt or overstretch the muscles. At the same time small sticky pads will be placed on your child's legs to measure muscle activity.

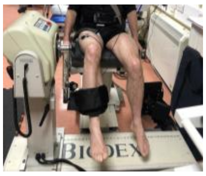

Figure 1: Dynamometer measuring knee strength

The researcher will also measure your child's range of motion at the knee and ankle using a goniometer (*see figure 2a and 2b*) and measure Selective motor control, using a clinical tool called SCALE (Selective Control Assessment of the Lower Limb). During the SCALE assessment your child will be asked to move different joints independently of one another and this will be video recorded to enable the researcher to score their selective motor control ability.

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*Figure 2 (a) Measurement of knee range of motion*

*Figure 2 (b) Measurement of ankle range of motion*

Lastly your child will be asked to complete 6 Everyday walking tasks in bare feet, with or without their walking frame (depending on your own preference and walking ability), wearing a small motion sensor box on the ankle, hip and knee, of their most affected leg (See figure 3). The everyday walking tasks we will ask your child to complete are as follows.

1. Walking along a 5metre level walkway at a self-selected (with or without walker)
2. Walking along a 5metre level walkway at a fast speed (with or without walker)
3. Walking up a slope with railings (with or without walker)
4. Walking down a slope with railings (with or without walker)
5. Walking up 3 steps with railings
6. Walking Down 3 steps with railings

For examples of everyday walking tasks please see pictures below:

*Figure 3. From left to right, Example of 5m level walkway task wearing motion sensors, 3 step task wearing mortion sensors and an example of the slope walking task*

This study will all be carried out during a one-off assessment, which will take approximately 90mins in total. You will be reimbursed for any reasonable travel expenses incurred as a result of participating in the study. We currently pay 45p/mile. Please contact us if you feel your travel expenses will be above £30.

You should continue your usual medication regardless of the study. You should not undertake the study if you show any signs of infection and illness (high temperature, vomiting, and diarrhoea) on the planned day of assessment.

**Are there any side effects?**
Your child may find the tests tiring to complete. There is the possibility that the muscles may feel tired and a bit sore the next day. We will provide rests periods between measurements and stop tests if they cause any discomfort.

**What are the possible benefits of taking part?**
You are helping to improve our understanding of crouch gait during everyday walking activities and helping to shape future treatment options for children and young people with cerebral palsy.

**What happens when the research study stops?**
We will analyse the data and then aim to publish it in a scientific journal. We can send you summary of the study. This study will inform a future study looking at using muscle stimulation to help manage crouch gait.

**How will we use information about you and your child?**
We will need to store you and your child's initials/ name/ contact details for the study duration and afterwards if you want a study summary. This will allow us to contact you to arrange appointments and send you study reports. Your personal details will only be seen by the immediate research team.

The data gathered from the tests will be compared to other children with cerebral palsy and children of a similar age who do not have cerebral palsy. We will assess whether measures such as strength and stiffness can predict how much the knee moves while walking.

The film from the video cameras will be used to assess your child's selective movement ability. We will pixelate the video so your child will not be identifiable in this video. The research team will use the videos to grade your child's movement ability.

We will keep all information about your child safe and secure. People who do not need to know your child's information, will not be able to see their name or contact details. Your child's data will have a unique code number instead. Once we have finished the study, we will keep some of the anonymised data so we can check the results. We will write our reports in a way that no one can work out that you 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. This will not affect their medical care or participation in other studies in anyway. If your child wants to stop during the measurement session, we would like keep information about you that we already have. After the study the data is anonymised, and we cannot withdraw the data.

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

In this research study we will use information from your child. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules.  At the end of the study we will save some of the data in case we need to check it and for future research.

We will make sure no-one can work out who you are from the reports we write. The information pack tells you more about this. The information pack is at the end of this sheet.

**What will happen if we don't want to carry on with the study?**
You and your child can withdraw from the study at any time without giving a reason. Whatever decision you make will not affect the care you in anyway. Should your child decide to withdraw from the study, the measurements we have collected up to that point will be kept and used in analysis of the results unless you ask that they are also withdrawn. You can withdraw your child during the measurement if they become upset or distressed or no longer want to participate for any reason.

**Who has funded and reviewed the research?**
This research has been funded by the Torbay Medical Research Fund and it has been reviewed by independent experts external to Plymouth University. Ethics approval has been gained for this study from the ……………………….

**What should I do if we are interested in taking part?**

If you and your child are interested in the study, please return the reply slip or contact Harriet Hughes via email or phone (contact details are given at the end of the sheet). She will then contact you to see if you have any further questions. If you are happy to participate, we will arrange an appointment to meet to carry out the study assessment.

**What if there is a problem?**
In the unlikely event that your child is harmed by taking part in this study, there are no special compensation arrangements. However, neglectful harm will be covered by the insurance scheme of the University of Plymouth which is leading on this study. If you are harmed due to someone's negligence, you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about this study, the normal National Health Service complaints mechanisms are available to you.

If you have a concern about any aspect of this study, you should speak to the research team who will do their best to answer your questions.

- Harriet Hughes
Study Co-ordinator and Physiotherapist
University of Plymouth PL4 8AA
Email: Harriet.hughes-5@postgrad.plymouth.ac.uk Tel:07894167523

- Professor Jon Marsden
Chief Investigator
University of Plymouth
Email: jonathan.marsden@plymouth.ac.uk Tel: 01752 587 590

If you would like independent advice about the study you can contact the University faculty of health administrators by e mail using FOHEthics@plymouth.ac.uk

Contact for further information If you would like any further information about this study, please contact:

Prof Jon Marsden
Professor of Rehabilitation
School of Health Professions
Faculty of Health Science
University of Plymouth,
Email jonathan.marsden@plymouth.ac.uk

You should be given a copy of this information sheet and a signed consent form to take home.

Thank you for reading this and considering whether to let your child take part in the project. If you are interested in taking part in this study and you are happy for the researcher to contact you then please complete attached contact reply form. Alternatively, you can email, phone, or send a whatsapp message/text to:

Harriet Hughes.

Study Co-ordinator and Physiotherapist
University of Plymouth PL4 8AA
Email Harriet.hughes-5@postgrad.plymouth.ac.uk:
Tel:07894167523

## Appendix: Information pack about data storage

### How will we use information about you?

We will need to use information from your child for this research project. This information will include you and your child's name and contact details. We will store the data we gather under a unique non-identifiable code. People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you 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 you took part in the study.

### What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your 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.

All information will be handled in compliance with the General Data Protection Regulations (2018). The University of Plymouth is the sponsor for this study based in the UK. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

Individuals from the University of Plymouth and regulatory organisations may look at your research records to check the accuracy of the research study. The research team will pass these details to the regulatory organisations along with the information collected from you. The only people in the University of Plymouth who will have access to information that identifies you will be people who need to contact you to arrange an appointment or to provide a summary of study findings or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name or contact details

### 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 using the contact details at the end of the information sheet
- by sending an email to the University Data Protection Officer at dpo@plymouth.ac.uk
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  The University of Plymouth privacy notices can be assessed at https://www.plymouth.ac.uk/your-university/governance/information-governance/privacy-notices